

**SAMHSA’s Fetal Alcohol Spectrum Disorders (FASD) Center for Excellence
Screening and Brief Intervention Project (SBI)**

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 Screening and Brief Intervention (SBI) project. 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 eight data collection instruments (Attachment I).

Alcohol Screening Instruments

- A Alcohol Brief Intervention First Visit Screening Questions with Aberdeen
- B Alcohol Brief Intervention First Visit Screening Questions with T-ACE (Tolerance, Annoyed, Cut down, Eye-opener)
- C Alcohol Brief Intervention First Visit Screening Questions with TWEAK (Tolerance, Worried, Eye-opener, Amnesia, and K/Cut down)

Brief Intervention Instruments

- D Alcohol Brief Intervention Follow up Visit Questions
- E Process Information About Visits for Women that Screened Positive First and Subsequent Visits
- F Follow-up with Women Referred for Assistance to Stop Drinking
- G Follow up After the Child Was Born
- H Client Participation Tracking (Eligibility through Follow-up) Form

The first three screening instruments are used at different sites and each site will use one of the three screening instruments. After screening, all sites will follow the same intervention protocol and use the five standard intervention instruments described above.

The screening and brief intervention is being integrated into current service delivery organizations at seven sites which are either WIC (Women, Infant, and Children) or Healthy Start Programs with all female clients who screen positive for alcohol use (all sites are listed in Attachment II).

Consistent with federal efforts to address issues of accountability, capacity, and effectiveness the integration of the screening and brief intervention 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 the screening and brief intervention

by measuring whether abstinence or reduced intake of alcohol is achieved as women progress through the intervention. In addition process information about subsequent visits and referral to treatment are also obtained.

Using the protocol developed by O'Connor and Whaley, each of the seven participating WIC and Healthy Start programs will screen pregnant women (clients) to identify those who are at-risk (currently drinking). Using an integrated service delivery model, identified clients will be followed within their WIC and Healthy Start programs and therefore relatively low attrition rates are expected (<5%). The SBI focuses on 10 to 15 minute sessions of counseling by a nutritionist, who will use a scripted manual to guide the intervention. Participants in the SBI will be assessed at each visit (to monitor alcohol use), referred for additional services to support their efforts to stop drinking, and will be provided a 10-15 minute intervention. Clients will be followed up until their 36th week of pregnancy.

At baseline, a survey administered by the WIC or Healthy Start manager will be used to assess pregnant women at the participating site health care delivery programs. Women will be assessed for risk using the T-ACE or TWEAK instruments which have been used successfully with pregnant women. Both quantity and frequency of drinking will be assessed. In addition, basic demographic data will be collected (age, race/ethnicity, education, and marital status) at baseline but no individually identifiable information will be recorded

Follow-up data will be collected by the WIC or Healthy Start case manager on a monthly basis as clients return for their WIC or Healthy Start program. At each monthly follow-up visit, drinking will be assessed and the client's goals for drinking will be recorded. In addition, process level variables will be assessed to understand how the program is being implemented (e.g. whether SBI was delivered; what referrals were made; which referral services were received). At the 36th week of pregnancy, drinking will be assessed and the client will be asked for permission to place her record from this program into her infant's medical record (upon delivery).

Background of Program and Legislative Requirements

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.

2. Purpose and Use of Information_

The practical utility of this new project is to collect data from sites to monitor the implementation of brief counseling interventions with low-income pregnant women at risk of having a child with a FASD.

Purpose of Data Collection:

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

- How many women enter the program and are identified as drinking alcohol, binge drinking or drinking at levels warranted for referral?
- How many women receive the SBI (that is, the brief intervention)?
- How many women are referred to alcohol treatment?
- How many women receive follow-up screening?
- How many women achieve abstinence as a result of fewer screening and brief intervention sessions?
- How many women remain abstinent at the end of the SBI follow-up period (the 36th week of pregnancy)?

As a result, a minimum data set will be collected to determine progress of this project as they are integrated at the sites.

Baseline Alcohol Screening Measures

The Screening and Brief Intervention projects will use quantity/frequency questions based on the Whaley/O'Connor measures, and the National Outcome Measure for alcohol use (number of days had a drink in past 30 days), as well as the TWEAK or T-ACE. (One site, Aberdeen, has modified the screening questions in the T-ACE so that they are culturally relevant for their population.)

Whaley and O'Connor¹ used self-administered quantity-frequency questions to measure alcohol consumption before the women knew she was pregnant and after she knew she was pregnant and timeline follow-up type questions. They demonstrated that these questions significantly increased the reporting of alcohol use among pregnant women relative to the usual assessments used by WIC clinics in southern California. T-ACE and TWEAK have been used successfully with pregnant women to detect alcohol use.²⁻⁵ A positive T-ACE or TWEAK for pregnant women is a score of 2.

The objective of the SBI program is to prevent alcohol-exposed pregnancies. Some women may not report current drinking and may have a positive TWEAK or T-ACE score. Therefore, this program will be administered to these women, as well.

GPRM Measures:

For this project, SAMHSA's 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 study 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 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, CSAP contractors and grantees.
- WIC and Healthy Start program staff, counselors, nutritionists that to promote health improvement at the individual and organizational levels.
- The chartered 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.

Funds for this research have already been set aside by CSAP; the contractor fully intends to complete the study with the designated funds.

3. Use of Information Technology

Data will be collected directly by staff in each of the seven WIC or Healthy Start Programs, and then be transferred electronically to SAMHSA's contractor and subcontractor.

First, new data collection will be gathered by case managers during face to face meetings with pregnant women seeking prenatal care through WIC and Health Start Programs administered by seven subcontractors. The estimate is that 3,428 respondents annually will participate in baseline and then 85% will be followed for a maximum of 4 months through delivery. As surveys will be administered by trained case managers and other staff, accommodations will be made on an as needed basis to ensure full participation of willing respondents.

The case managers conducting the survey will enter responses onto paper surveys or directly into a locally installed electronic database designed by the subcontractor. Survey data will be entered into the database and stored electronically in secured files. Standard procedures to protect data, 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 subcontractor dedicated Windows-based server are also encrypted. Access to data on the subcontractor server is username and password protected.

For reporting and analysis purposes, the FASD Center for Excellence will use Microsoft Access to prepare comprehensive data files for individual sites. These individual site data files will be submitted to CSAP's Data Analysis Coordination and Consolidation Center (DACCC) in April and October (or annually as appropriate). SAMHSA's DACCC and the subcontractors have identified common data measures for FASD treatment and prevention. In conducting any secondary analysis of the data SAMHSA's DACCC will only combine the data for sites that have used the same screening tool. Data will not be aggregated across sites for purposes of analysis or reporting. 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 project (5/31/2012).

Burden for sites is eased by subcontractor's development of a database for 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 contractor site.

Many of the women who seek prenatal care through WIC and Healthy Starts use English as a second language. To facilitate maximum participation, screening instruments (TWEAK and T-ACE) were translated and are available for use in Spanish.

4. Efforts to Identify Duplication

The data collection proposed for this evaluation is not available elsewhere, is not duplicative, and is seen as critically valuable for assessing the effectiveness of Alcohol Screening and Brief Intervention. 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 included in these surveys. It is important to stress that individual respondents are not being asked to provide information about them which has been collected elsewhere.

5. Involvement of Small Entities

There is no significant involvement of small entities.

6. Consequences if Information Collected Less Frequently

Each respondent will participate at monthly prenatal visits throughout the duration of her pregnancy. Participation is voluntary; respondents are free to refuse to participate. While anticipated response is expected to be high since the intervention is provided during the course of normal WIC or Healthy Start Program delivery, the estimated response over the course of the project is estimated to be 85%. Factors influencing response rates include: a) If a previously identified participant refuses to participate during one of her prenatal visits; b) loss of pregnancy; c) missed appointments; etc. Federal reporting requirements would be unmet if data were not collected. The Center is required to submit data to the CSAP DACCC for analysis twice per year (October and April). These submission dates are necessary for SAMHSA/CSAP to provide the

most current performance reports to GPRA. If these data are submitted to SAMHSA/CSAP less frequently, SAMHSA/CSAP will not be able to meet such reporting requirements.

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 October 30, 2008, Vol. 73, No. 211, Pages 64620-64621. No written comments were received.

Below are summaries of the outside consultations (separate from the publication of the notice in the *Federal Register*) regarding proposed data collection instruments -

- First, Contractor conducted extensive discussions with the sites to ensure information is clearly presented and collected in 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. As a result, the data collection instruments use plain, coherent, unambiguous terminology and are understandable to users.
- Second, the SAMHSA FASD Center for Excellence sought consultation outside of the agency from its evaluation subcontractors at the Human Services Research Institute while developing the proposed forms. The evaluation 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 actionable data. Evaluators at the Human Services Research Institute 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/Subcontractor Project Director
(617) 844-2506

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

9. Payment 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 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 privacy is protected 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 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 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 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.
- The data collected by the sites for the program 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 while pregnant and to what extent. 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 substance abuse 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. Since all of the participating agencies have informed consent documents (Attachment III) that they currently are using in their programs, slightly different consent forms will be used by each participating agency. All consent forms will inform respondents in the instructions to the surveys 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 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 enrolled either in WIC or Healthy Start programs. Based on the populations served in these programs, we estimate that approximately 20% of clients will be unemployed and that the remaining 80% will receive minimum wage (currently \$6.55/hour).

Estimated annualized burden hours

Instrument / Activity	No. of Respondents	No. of Responses per Respondent	Average Burden per Response	Total Burden Hours per Collection	Hourly Wage Cost	Total Hourly Cost (\$)
Client Surveys: Assessment/ Baseline Data Collection (Form A, B or C)	3,428	1	.25	857	\$6.55	\$ 5,613.35
Client Surveys: Monthly Follow-up (85% of baseline x 4 months maximum) (Form D, E and F)	2,914	4	.21	2,448	\$6.55	\$ 16,034.40
Assessment Data Collection at 36 th week (85% of baseline) (Form D, G, and H)	2,914	1	.16	466	\$6.55	\$3,052.30
TOTALS	3,428		---	3,771	---	\$ 24,700.05

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

There is no capital, start up, operational, or maintenance service costs related to this data collection activity.

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 \$1,205,730.

SAMHSA /CSAP estimates the GS-15 Government Project/Task Order Officer (GPO/TOO) principally involved in the oversight and analysis of this contracted evaluation 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 \$1,206,486.

15. Changes in Burden

This is a new project.

16. Time Schedule, Publication and Analysis Plans

The current contract for the SBI program ends 5/31/2012. A report is to be delivered by this date to CSAP. The Table below outlines the project schedule with timelines for data collection, analysis, report delivery and presentation to stakeholders.

<i>Activity</i>	<i>Planned Start Time</i>
<i>Train programs on submitting data to Contractor</i>	<i>OMB approval + 2 weeks</i>
<i>Transmit baseline data from Alcohol Screenings</i>	<i>OMB approval + 3 weeks</i>
<i>Transmit monthly Brief Intervention episode data</i>	<i>OMB approval + 4 weeks</i>
<i>Develop quarterly data reports</i>	<i>OMB approval + 12 weeks to coincide with project reporting periods, each year, of: February 1 May 1 August 1 November 1</i>
<i>Submit data for SUBCONTRACTOR to produce final report and recommendations</i>	<i>Data for Oct 2008 through October 2011, to be submitted to Contractor and SUBCONTRACTOR by 1/15/2012 (Subcontractor's report due 3/30/2012)</i>
<i>Deliver Final Files</i>	<i>By 3/30/2012</i>
<i>Send project documentation</i>	<i>End Of Contract 5/31/2012</i>

Analysis Plan

Almost all survey items are closed-ended questions; many of which are "yes" or "no" items. (Respondents will be given the opportunity to add clarifying comments regarding their responses. These will be written down by trained case managers, nutritionists or other staff.) Basic statistics will be calculated to derive frequency distributions, means, and other measures of central tendency for sites individually. 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.

As sites will be using one of three screeners to identify participants, we acknowledge that this approach allows for the possibility of different participant populations at each site. Because of this, cross-site analyses will be not conducted with any resulting data. The comparison of "number of drinks" across sites will bear a caveat identifying that data is based on potentially different populations of participants at each site, and that statistically valid comparisons across sites cannot be drawn from this data.

T-tests will be performed to compare the first visit screening questions with TWEAK/T-ACE scores upon entry in to the program and upon exit and follow-up times.

Two sample table shells are shown below.

Sample Table Shells Highlighting Important Analyses

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

	t-test	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)	
		Baseline response	Post-Intervention response
WIC Agency 1			
WIC Agency 2			
Healthy Start Program 1			
Etc			

	t-test	T-ACE or TWEAK SCORES Baseline and Exit (reported as number of clients)			
		BASELINE SCORE		POST-INTERVENTION SCORE	
		0-1	≥2	0-1	>2
WIC Agency 1					
WIC Agency 2					
Healthy Start Program 1					
Etc.					

Unique Identifier

Each client will be assigned a unique identifier which meets HIPAA requirements for privacy. Most sites will adopt subcontractor’s proposed convention for a multi-level identification number in the format of “xxxxzzz-yyyy” (with “xxxxzzz” 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, generated by subcontractor, may be sub-divided 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

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. Whaley, S. and O'Connor, M. 2003. Increasing the report of alcohol use among low-income pregnant women. *American Journal of Health Promotion* 17(6):369-372.
2. Centers for Disease Control and Prevention 2004. *Fetal Alcohol Syndrome: Guidelines for Referral and Diagnosis*. Atlanta, GA: U.S. Department of Health and Human Services.
3. National Institute on Alcohol Abuse and Alcoholism 2002. Screening for alcohol problems—An update. *Alcohol Alert* 56. Bethesda, MD: National Institutes of Health.
4. Chang, G. 2001. Alcohol screening instruments for pregnant women. *Alcohol Health & Research World* 25:204-209.
5. Cherpitel, C.J. 1997. Brief screening instruments for alcoholism. *Alcohol Health & Research World* 21:348-351.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

Seven sites from across the U.S. have been selected to participate in implementing the SBI project. All women who are seeking prenatal care through government sponsored programs, WIC and Healthy Start in locations operated by the selected sites will be asked 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 H. As described above, the sampling plan is purposive. Each survey respondent will be provided information on their first prenatal care visit detailing the purpose of the request for their participation, their right not to participate, how their information will be handled and protected.

Screening Form (Form A, Form B, Form C)

The screening form determines whether or not women are eligible to receive the brief intervention. This form is administered once at the beginning of the intervention. Clients will either receive Form A, Form B, or Form C depending on the site.

There are two criteria for eligibility: being pregnant, and drinking any alcohol whatsoever during pregnancy. To qualify, clients need to be:

- At least 1 week pregnant
- Have drank alcohol 1 or more days in the past 30 days (answer to Question 6 on screening form is greater than or equal to 1) OR receive a score of 2 or more points on EITHER the TWEAK OR the T-ACE OR Aberdeen site screening form.

Follow-Up Visit Questions (Form D)

The follow-up visit questions assess the current drinking levels for the client and also determines the outcomes of the intervention (e.g., has the client stopped drinking alcohol?). The follow-up visit questions are asked at each visit and at 36th week of pregnancy (e.g., the form is completed multiple times).

Process Information (Form E)

“Process” information is documented after each visit (again, this form will be completed multiple times for each participant). This form documents information about whether and how the interventions were provided.

Referrals for Assistance to Stop Drinking (Form F)

As part of the brief intervention, the service provider conducts their own assessment to determine whether a client needs additional assistance to stop drinking alcohol during pregnancy. The assessment itself does not need to be documented, but the form does record what happened after the clinician completed that assessment. Since there is the potential for multiple referrals, this form may be completed multiple times per participant.

Follow-Up After Birth of Child (Form G)

The last point of data collection occurs after the client gives birth to the “target child.” Only one piece of information needs to be recorded after the birth of the child – a “yes or no” question about whether the client’s record, including whether she drank during pregnancy, was sent to the child’s pediatrician or physician. This question only needs to be answered once.

Client Participation Tracking Form (Form H)

This form will be used to keep track of clients participating in the program from eligibility through follow-up. In instances when a client refuses to participate or if the client can’t be located the case manager will record the relevant information on the form.

3. Methods to Maximize Response Rates

The evaluation subcontractor will work with contractor to assist the sites in creating appropriate evaluation plans. This process is also a partnership. The expectation for evaluation will be articulated in the SOW and will be communicated early and reinforced often.

Response rates have been estimated at 85% across all of the participating programs. Subcontractor’s strategy to help sites maximize their response rates and minimize burden on respondents relies upon establishing rapport with clients from the start of the first session and includes more specific strategies such as:

- 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 (screening, monthly 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 send a reminder email to clients a few days before their upcoming appointment, to reduce the chance of a missed appointment.
- c. At screening, requesting the name, phone number, and email address of both a relative and close friend of the client. Obtaining the client’s permission to contact the friend and relative for help locating the client as needed for follow up.
- d. 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).
- e. Sending postcards to clients every six months asking them to confirm their address or update you with their new address.

4. Tests of Procedures

All survey instruments were reviewed by the subcontractor evaluation team during the fall of 2008. All instruments were then pilot tested at the sites (one per site). Subsequent revisions were made to these forms based on their feedback. The lost to intervention or follow-up form was also added as a result of obtaining feedback from the sites.

5. Statistical Consultants

Data collection will be conducted at the seven sites that are integrating the SBI project. The task lead for the FASD Screening and Brief Intervention, Vinitha Meyyur, Ph.D. will oversee the sites. Data analysis will be performed by the evaluation subcontractor, Human Services Research Institute under the supervision of the Project Director, Virginia Mulkern, PhD.

<u>Contractor:</u>		<u>Phone</u>
Vinitha Meyyur Ph.D.	Northrop Grumman Corporation	301-527-6512

<u>Sub Contractors:</u>		
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 Alcohol Brief Intervention First Visit Screening Questions with Aberdeen
- B Alcohol Brief Intervention First Visit Screening Questions with T-ACE
- C Alcohol Brief Intervention First Visit Screening Questions with TWEAK
- D Alcohol Brief Intervention Follow up Visit Questions
- E Process Information About Visits for Women that Screened Positive First and Subsequent Visits
- F Follow-up with Women Referred for Assistance to Stop Drinking
- G Follow up After the Child Was Born
- H Client Participation Tracking Form

II List of FASD Screening and Brief Intervention Sites

III Informed Consent Forms