SAMHSA Fetal Alcohol Spectrum Disorders (FASD) Center for Excellence
Parent-Child Assistance Program

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 Parent-Child Assistance Program (P-CAP). The purpose of the FASD Center for Excellence (CFE) is to prevent alcohol exposed pregnancies among women of childbearing age and pregnant women (18 and above); and improve the quality of life for individuals affected by FASD.

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

A. The Community Referral Screening Questionnaire (CRSQ)
B. The Addiction Severity Index (ASI) Part A
C. The Addiction Severity Index (ASI) Part B
D. The Demographic Questionnaire
E. The P-CAP Weekly Advocate Time Summary Sheet
F. The Monthly Update Form
G. The Biannual Documentation of Progress
H. The Exit ASI Follow-Up
I. The Client Exit Close-Out Form
J. The Advocate Accounting of Tracing Activity on Missing Post-Exit Client
K. The Lost Post-Exit Client 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.

The purpose of this data collection effort is to monitor the integration of the evidence-based intervention (P-CAP) into existing service delivery organizations. The FASD Center for Excellence will integrate the P-CAP program at two sites. A description of the P-CAP program and forms to be used at different time points of the intervention is described below. The FASD Center for Excellence in integrating this intervention intends to monitor and collect process level information measures on home visits, counseling sessions, and time spent with clients. In

addition abstinence from alcohol use will be measured by determining any change in alcohol consumption at different time points which will be calculated as a percent decrease in consumption.

The P-CAP intervention was developed for high risk women who misuse alcohol and drugs during pregnancy, and has been rated and officially recognized as a Promising Program by SAMHSA's National Registry of Effective Programs and Practices. P-CAP is a paraprofessional home visitation model for extremely high-risk women. The program uses a case management approach, an effective complement to traditional substance abuse treatment, and focuses not simply on reducing alcohol and drug use, but on reducing other risk behaviors and addressing health and social well-being of the mothers and their children. The goals of the program are to: (1) assist mothers in obtaining treatment, maintaining recovery, and resolving the complex problems associated with their substance use; (2) guarantee that the children are in a safe environment and receiving appropriate health care; (3) effectively link families with community resources; and (4) demonstrate successful strategies for working with this population in order to prevent the risk of future drug and alcohol-affected children.

P-CAP is being integrated into service delivery organizations at two sites (Attachment II). The P-CAP screening form is administered to all women at risk of alcohol abuse at the participating sites. Women are eligible for the P-CAP program based on their consumption of alcohol; and pregnancy status or 6 months postpartum (18 and above). After screening sites will administer the ASI Intake and the demographic survey tools to all women enrolled in the program. Case managers (referred to as advocates) assist clients in obtaining alcohol and drug treatment and staying in recovery, and connect at-risk women with community resources that can help them achieve their individual clinical goals for a period of three years. Weekly Advocate Time Summary is administered on a weekly basis, the form tracks time spent on the phone, in person, or providing transportation to each client. Changes in alcohol and drug use, contraceptive use, and connection to community services are assessed monthly and biannually throughout the program which lasts for 3 years. The ASI Exit is administered at program exit. The Client Exit Close-Out form documents the total number of months the client spent in P-CAP, number of different advocates who worked with the client, and whether the client ever moved out of the area while enrolled in P-CAP. The Advocate Accounting of Tracing Activity on missing post-exit client is used to track activity to locate a missing client. When a client is missing, the form is to be completed each month, instead of the Monthly Update form, until the missing post-exit client is brought in for and Exit Interview. The Lost Post-Exit Client Form is used when the client is at least six months past her three-year exit date in the program and has not completed the ASI exit interview. The form documents the reason the client has not completed the ASI exit interview.

Consistent with federal efforts to address issues of accountability, capacity, and effectiveness the integration of P-CAP at the sites will advance the field of FASD prevention and treatment by learning what works in specific settings with specific populations (women in treatment settings).

Parent-Child Assistance Program (P-CAP)[1]is an evidence-based program that uses an intensive paraprofessional home visitation model to reduce risk behaviors in women who are pregnant or up to 6-months post partum and who are in drug abuse treatment or alcohol treatment. Women

are assessed at baseline for alcohol use. The P-CAP model of paraprofessional advocacy is grounded in relational theory, which highlights the importance of interpersonal relationships in women's treatment and recovery, while also emphasizing the application of practical techniques based on motivational interviewing, stages of change theory, and harm reduction. The goal of the FASD project which integrates the P-CAP program at the sites is to prevent alcohol-exposed births among women who are at risk.

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 P-CAP case management intervention 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 P-CAP interventions were provided (and to document the details of the intervention as they are integrated), and 2) assess the extent to which women achieved abstinence from alcohol use and consistent and correct use of contraceptive methods over a period of time. Abstinence from alcohol use and effective contraception use will be calculated as a percent difference between two time points. 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 (pregnant and postpartum women who are using alcohol)?
- How many women participate in P-CAP?
- How many women achieve abstinence from alcohol at monthly and biannual visits?
- How many women continue to achieve abstinence at the end of three years?
- How well P-CAP is integrated into the existing organizations?
- Is P-CAP being implemented as intended? (fidelity)

Alcohol Screening Measures

At baseline, the CRSQ will be administered by an advocate to assess drinking, contraceptive use, and demographic information. Eligibility is determined based on response to questions on drinking behavior, pregnancy status and women up to 6 months postpartum who are at risk are also eligible to enroll. All eligible women will receive case management on a monthly basis through home visits.

At the end of each case management session the case manager records basic information about the session (date, time spent with the client, use of alcohol, contraception use, and employment status). At the end of the intervention women will be administered the ASI exit and assessed on their alcohol consumption and contraceptive use in the past 30 days.

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. The findings from this data collection effort can only be replicated at similar settings and population groups. The findings cannot be generalized to the population at large or to populations of pregnant or postpartum women. Since this program is being integrated at a setting where women receive treatment for alcohol and substance use, its findings are representative of only that setting. 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.
- 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),
- 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 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 two participating sites during face-to-face meetings with pregnant/postpartum women. The advocates administering the survey will enter responses onto paper surveys or directly into a standardized web-based 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 unauthorized access. 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 which is web based.

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 P-CAP. 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 from screening through the end of intervention. Specifically data collection will occur at screening, during the intervention phase (monthly and biannually) and end of program (at the end of three years). P-CAP intervention is designed to collect data every month and biannually from screening through end of the intervention which lasts for 3 years. Collecting data less frequently will not pose a problem in terms of reporting data to SAMHSA because data is collected on a monthly basis and if data cannot be recorded on a client for a particular month the advocates make an effort to consistently locate the women and follow-up with them so they will be able to administer the Monthly Update form at least the following month. So if a client misses one monthly session data will still be available for the client for the remaining 35 months.

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 April 22, 2009, Vol.74, No. 76, pages 18386-18388. 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 contractor consulted with Dr. Therese Grant and other lead researchers who originally developed the P-CAP program in order to replicate the existing intervention protocol as closely as possible. Dr. Therese Grant will also provide training to the awarded sites to ensure that each agency has a clear and comprehensive understanding of the data collection instruments. All of the P-CAP instruments were adapted to integrate the P-CAP program into the service delivery organizations.

- 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:

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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 (IRB requirement was waived by SAMHSA). 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 the consent process is as described. Each client is administered the CRSQ to determine eligibility in the program. If eligibility is confirmed, the client is provided with information about the P-CAP program and invited to participate. Each program uses the consent form to go over the program components, expectations, and assurances. If the client agrees to participate, the form is signed by the client and the clinical supervisor.

Nonetheless, participation in this intervention is voluntary. The minimal requirement for the participants would be to respond to questions on the screener. All other forms are voluntary and not responding to the questions on those forms does not affect participation. The client service agreement form and the consent form administered by each of the sites inform respondents about the purpose of data collection, that their information will be kept private and that they are free to skip any question that they do not wish to answer. Each of the participating sites has informed consent documents (Attachment III) that are slightly different because they are integrating P-CAP into their existing service delivery systems. 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)].

Each of the grantees have signed or will sign a Data Use Agreement with the Center for Excellence so that they may share data on clients participating in the program with the Center for Excellence (and the evaluation subcontractor). As outlined in the HIPAA regulations, this agreement will allow the grantees to disclose "a limited data set" to be used for research (in this instance). The limited data set will protect the privacy of the clients since it will exclude the release of all of the following types of data:

- Names;
- Postal address information, except town or city, State, and zip code;
- Telephone numbers;
- Fax numbers;
- Email Addresses;
- Social Security Numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/ license numbers;
- Vehicle identifiers and serial number, including license plate numbers;
- Web URL's;
- IP addresses;
- Biometric identifiers, including finger and voice prints; and
- Full face photographic images and any comparable images.

Data which are permitted with a Data Use Agreement and which will be collected in P-CAP include:

- dates such as admission, discharge, service, DOB;
- state of residence; and
- Age in years, months or days.

Any data which could be used to identify an individual will not be released by the Center for Excellence or its evaluation subcontractor (e.g. DOB in a small community or geographical region where such disclosure would likely identify an individual.).

In order to further ensure privacy and comply with HIPAA, both the Center for Excellence and its evaluation subcontractor will use the information in a manner that is consistent with the Data Use Agreement and will employ safeguards to ensure that respondent privacy is protected. Reporting templates will be designed for the grantees which explicitly exclude all protected information and only include data to be reported for the program. Should any information which

is not covered by the Data Use Agreement be released, the violation of HIPAA will be reported to SAMHSA.

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. The purpose of collecting this sensitive information is to address the issue of alcohol use and consistent use of contraception to avoid an alcohol exposed birth or pregnancy. Only data which are necessary for the evaluation will be collected. The Federal Government has already established an interest in collecting this type of data.

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 80% of clients will be unemployed and that the remaining 20% will receive minimum wage (currently $7.25/hour).

Instrument / Activity	No. of Respondents	No. of Responses per Respondent	Total number of responses	Average Burden per Response	Total Burden Hours Collection	Hourly Wage Cost	Total Hour Cost
At Baseline /Enrollment:							
CRSQ	190	1	190	0.08	15	$7.25	$109
ASI- Part A	190	1	190	2.75	523	$7.25	$3,792
ASI- Part B & Twin	190	1	190	0.25	48	$7.25	$344
Demographic Data	190	1	190	0.08	15	$7.25	$109
Process Monitoring:							
Weekly Advocate Time Summary	190	52	9880	0.50	4940	$7.25	$35,815
Intermediate Outcomes:							
Monthly Updates	190	12	2280	0.50	1140	$7.25	$8265
Biannual Documentation of Progress (every 6 months)	161	2	322	0.33	106	$7.25	$769
At Exit:							
Exit ASI	190	1	190	2.25	428	$7.25	$3103
Client Exit Close Out form	161	1	161	0.25	40	$7.25	$290
Ad hoc:							
Advocate Accounting of Tracing Activity on Missing Post-Exit Client	29	1	29	0.25	7	$7.25	$51
Lost Post-Exit Client Form	29	1	29	0.25	7	$7.25	$51
TOTAL	190		13,651		7,269		$52,698

The Client Exit Close Out form, Advocate Accounting of Tracing Activity on Missing Post-Exit Client and a separate form and Lost Post-Exit Client Form is filled out by staff if the participants are not able to be located

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 direct costs (includes labor, travel and ODC) for the two sites. The direct cost for Michigan site is $ 283,531.15 and for the Southern California site it is $130,643.87. The labor cost for the evaluator to oversee the sites is $5,730.The total cost of this data collection effort being performed under a Task Order, is $419,905.

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 $420,661. This total is the cost burden and there is no additional cost to the government.

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).

Construction of measures

Below are details about how specific measures will be constructed. Frequencies of these measures will be reported.

The number of women who were referred for the P-CAP program will be calculated by counting the number of completed Community Referral Screening Questionnaires (Attachment I.A). The results of the Community Referral Screening Questionnaires will be used to calculate the number of women who met all three eligibility criteria for the P-CAP intervention: 1) currently pregnant or post-partum; 2) self-report of alcohol or drug use during this pregnancy; and 3) lack of involvement with community services such as prenatal care, mental health services, or other needed social services.

The number of women who participate in P-CAP will be calculated using a number of different sources. The number of completed ASI questionnaires will be used to compute a count of the number of women who completed an initial intake interview (Attachment I.B). The number of completed Biannual Documentation of Progress questionnaires will be used to document the number of women still participating in the P-CAP program after 6, 12, 18, 24, and 32 months (Attachment I.G). The number of women who have been declared lost on the Lost Post-Exit Client Form (Attachment I.K) will be used to calculate the attrition rate from the program, using the formula below:

$$\frac{\text{Total number of clients declared lost in the Lost Post-Exit Client Form}}{\text{(Total number of completed Exit ASI forms + total number of clients declared lost)}}$$

The Monthly Update Form will be used to determine the percent of women who report abstinence from alcohol at monthly and biannual visits (Attachment I.F). Abstinence rates will be calculated using question 2b, which asks the National Outcome Measure question "During the past 30 days, on how many days did you drink one or more drinks of an alcoholic beverage?" The following formula will be used:

$$\text{Percent Abstinent:} \quad \frac{\text{Number of women who reported that they drank for 0 days of the past 30}}{\text{Total number of women who completed a Monthly Update Form}}$$

The Exit ASI (Attachment I.H) will be used to determine the percent of women who report abstinence from alcohol at the end of the three-year intervention. End-of-program abstinence rates will be calculated using question D1, which asks clients to report the number of days they drank in the past 30 days. The following formula will be used:

$$\text{Percent Abstinent:} \quad \frac{\text{Number of women who reported that they drank for 0 days of the past 30}}{\text{Total number of women who completed an Exit ASI}}$$

Statistical analysis

Descriptive statistics (frequency distributions, means, and other measures of central tendency) will be reported for the demographic variables, service delivery variables, and the three primary outcome measures (use of alcohol, use of contraceptive measures, and alcohol exposed pregnancies). In addition, in order to assess whether the women have achieved the desired outcomes, inferential statistics will be used. SAMHSA requires data on the NOMS variable (drinking) to be collected at different time points during the intervention in order to determine change over time. The purpose of using the inferential statistics in not to draw any conclusions about the intervention but to determine if there was a decrease in the percentage of drinking over time.

Progress through the program will be assessed in three ways: by determining 1) change in outcome measures of interest upon entry to P-CAP to similar measures at 6-month and 12 months into intervention and at exit; and 2) differences in drinking measure to the dosage level of the intervention. Decrease in drinking levels may be compared with data from the evidence-based P-CAP program. However, it is unknown at this time if that analysis will be conducted.

The first set of measures will assess changes in outcomes (abstinence from alcohol, use of contraceptives, and absence of alcohol-exposed pregnancies) after receiving the P-CAP intervention. These analyses are described more fully below. The second set of measures (dosage level) will assess whether the number of contacts by the advocates and the amount of time spent by the advocate result in different reported levels of drinking overtime or between the two sites.

In addition to reporting change in percentage in drinking over time, data will be compared either over time or between the two sites participating in the current program; t-tests (for two time-points and to compare the two programs) will be used. The reason for comparing the 2 sites is that one site is local and the other is a state site.

As an example, the rates of abstinence at baseline will be compared with abstinence rates reported at post-intervention/exit from the program. The NOMs measure will be used and t-tests will assess statistical significance.

Table 1: Sample Table for Overall Analyses: Baseline vs. Post-Intervention

	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)
	(Number) Percent	(Number) Percent

Secondly, to determine if there are any differences across P-CAP programs, NOMs data will also be used and reported separately for each of the two P-CAP programs (sites) as outlined in the table below.

Table 2: Sample Table for Program-specific Analyses: Baseline vs. Post-Intervention

		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		(Number) Per cent	(Number) Per cent
Site 2			

Fidelity

Fidelity to the intervention will also be monitored. The Weekly Advocate Time Summary will serve as a process form that can be used to monitor progress of the program (Attachment I.E). When sites submit data bi-annually, counts of the number of completed intermediate outcome forms (the Monthly Update Form and the Biannual Documentation of Progress Form) will also be performed in order to monitor whether sites are appropriately assessing clients throughout the course of the long-term intervention. The following variables will be reviewed in order to assess the degree to which the intervention is being implemented as designed:

- number of weekly client visits provided by the advocate (Attachment I.E)
- amount of time the advocate spent face-to-face with the client every week (Attachment I.E)
- amount of time the advocate spent on the phone with the client every week (Attachment I.E)
- amount of time the advocate spent transporting the client every week (Attachment I.E)
- number of completed Monthly Update Forms relative to the number of clients who entered the program (Attachment I.F)
- number of completed Biannual Documentation of Progress Forms relative to the number of clients who entered the program (Attachment I.G)

In addition, the extent to which the programs have integrated P-CAP into their existing programs will be assessed through qualitative analysis of the sites' implementation plans and/or the program manuals (secondary data which does not require additional data collection from the programs). The bulleted list of variables above will be used to assess how well PCAP has been implemented. The qualitative data will allow us to look into broader categories of integration such as integration of existing policies, data systems, training protocols, and staffing.

Unique Identifier

Each client will be assigned a unique identifier which meets HIPAA requirements for privacy. Both 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 Excel to combine all individual responses into comprehensive data files. The forms used to collect data are being adapted from the P-CAP program and may contain some information on names and contact information of relatives and friends to help the staff stay in touch with the women over the 3 year time period. However, such information will not be transmitted to SAMHSA. The Center will submit individual site level data files to CSAP's Data Analysis Coordination and

Consolidation Center (DACCC) in April and October. 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. Parent-Child Assistance Program, University of Washington. 1991.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

Two sites from across the U.S. have been selected to integrate P-CAP into its current service delivery system (Southern California Alcohol and Drug Programs (local agency) and Michigan Office of Drug Control Policy (State agency)). The sites were selected based on a proposal submission and review process. The selection criteria for local and State agencies were slightly different. The review of proposal was conducted by the review team using the following selection criteria for local agency: 1) Service Delivery and Population Served, sub selection criteria included Program Capability and Need, Experience of Organization, Population Size and Age Groups 2) Technical Approach: sub criteria included Task Force and Needs Assessment Plans, Strategy and Sustainability, Brief Implementation Plan, Evidence-based FASD Prevention Interventions, and Evaluation and Data Collection Plan, and 3) Personnel and Management Plan: sub criteria included Expertise and Project Management. The review of proposal was conducted by the review team using the following selection criteria for State agency: 1) Service Delivery and Population Served, sub selection criteria included Program Capability and Need/Experience of Organization, Local Service Organizations, 2) Technical Approach: sub criteria included Task Force and Needs Assessment Plans, Strategy and Sustainability, Brief Implementation Plan, Evidence-based FASD Prevention Interventions, and Evaluation and Data Collection Plan, and 3) Personnel and Management Plan: sub criteria included Experience and Project Management. The two sites were chosen because they received acceptable scores on the selection criteria and served populations that were in treatment. 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.
The findings from this data collection effort can only be replicated at similar settings and population groups. The findings cannot be generalized to the population at large or to populations of pregnant or postpartum women.

2. Information Collection Procedures

Copies of the survey instruments are included in Attachment I as Appendices A through K. Information will be collected by staff at the specified time periods. Details on the purpose and timing of the administration for each of the instruments are provided below.

The Community Referral Screening Questionnaire (CRSQ)
The Community Referral Screening Questionnaire (CRSQ) is a screening form administered to individuals referred to P-CAP. The purpose of the form is to determine eligibility for enrollment in P-CAP.

The Addiction Severity Index (ASI) Part A
The Addiction Severity Index (ASI) Part A is an intake interview administered at client enrollment. The ASI Part A includes questions about past 30 day alcohol use, lifetime use, age at first use, month and year of last use, range of use (T-ACE), and use during pregnancy, thereby providing a thorough assessment of alcohol consumption.

The Addiction Severity Index (ASI) Part B
The Addiction Severity Index (ASI) Part B is an intake interview administered as soon as possible after the target childbirth. The ASI Part B includes questions about the target child at birth and alcohol use during the pregnancy. If the target birth is of twins then the Twins Addendum form is administered.

The Demographic Questionnaire
The Demographic Questionnaire is administered after client enrollment. The questionnaire includes race, educational attainment, marital status, and an alcohol assessment.

The P-CAP Weekly Advocate Time Summary Sheet
The P-CAP Weekly Advocate Time Summary Sheet is administered on a weekly basis. The form tracks time spent on the phone, in person, or providing transportation to each client.

The Monthly Update Form
The Monthly Update form is administered on a monthly basis. The form records any changes in drug and alcohol use, pregnancy, child custody, and sources of income.

The Biannual Documentation of Progress
The Biannual Documentation of Progress is administered every six months. The form documents changes in alcohol/drug treatment, abstinence from alcohol/drugs, birth control and pregnancy, connection to other services, and family stability and client activity.

The Exit ASI Follow-Up
The Exit ASI Follow-Up is administered at the end of the program, at 36 months. The Exit ASI uses a format that is identical to the Addiction Severity Index administered at intake, providing pre- and post-test data for the intervention.

The Client Exit Close-Out Form documents the total number of months the client spent in P-CAP, number of different advocates who worked with the client, and whether the client ever moved out of the area while enrolled in P-CAP.

The Advocate Accounting of Tracing Activity on Missing Post-Exit Client
The Advocate Accounting of Tracing Activity on Missing Post-Exit Client is used to track activity to locate a missing client. When a client is missing, the form is to be completed each month, instead of the Monthly Update form, until the missing post-exit client is brought in for and Exit Interview.

The Lost Post-Exit Client Form
The Lost Post-Exit Client Form is used when the client is at least six months past her three-year exit date in the program and has not completed the ASI exit interview. The form documents the reason the client has not completed the ASI exit interview.

3. Methods to Maximize Response Rates

The contractor (and a research subcontractor) has been working with the P-CAP sites to create appropriate monitoring/evaluation plans. The estimate is that 190 respondents annually will be assessed across the 2 sites, of which 85% (or 161) will participate in P-CAP and will be available to complete the biannual forms. However, since P-CAP has a very well designed process to follow up and stay in touch with the women in the program we estimate that all of the women will be able to fill out the ASI exit form at the end of the program. 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. This information is tracked on all Monthly Update forms to closely track clients and to identify clients with missing data and follow them.
b. In addition the Client Exit Close Out form, Advocate Accounting of Tracing Activity on Missing Post-Exit Client, and Lost Post-Exit Client Form is filled out by staff if the participants are not able to be located. Implementation of these forms helps maximize the response rates because the staff can consistently track the clients at various time points in the program and can quickly locate the clients based on eth information gathered.

Reducing Attrition

a) The P-CAP program has a theoretical foundation based on relational theory and stages of change (including an emphasis on self-efficacy, and using motivational interviewing). The entire model is based on the effort to develop trust with and keep track of the clients. We train advocates on strategies for developing this relationship and building trust. In addition we train advocates on tracing strategies should the client disappear, although a core component is that clients are not asked to leave the program because of relapse or setbacks.

b) The P-CAP program maintains a focus with the advocates on the importance of keeping track of the clients, and on methods to get/keep clients engaged. For example, we enter tracking information from the intake client face sheet into an Access database. Tracking sheets with contact information are updated every 6 months by the advocates; the information is then entered into the database so that the database always has current contact information.

c) Advocates are trained to focus on keeping the information up to date, not to lose track of clients, and to find the client should she drop from sight. Supervisors also track advocate involvement with clients by looking at the Weekly Advocate Time Summary sheets to make sure advocates are seeing clients regularly.

4. Tests of Procedures

All survey instruments were pilot tested among the project team members in fall 2008. As part of the pilot testing process each of the two sites was provided copies of all survey tools for comments and feedback. Sites were informed that the forms from the PCAP program will be used in this program since we are integrating the PCAP evidence-based program. Sites did not have any revision to the forms and were willing to use them as is. Nine pilots were completed at both sites combined. The CFE added one form to the already existing set of P-CAP forms. This form is the demographic survey form. This form was added to elicit data on SAMHSA NOMS and includes demographic data and questions on drinking behavior.

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 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.

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List of Attachments

I In-Person Surveys

A. The Community Referral Screening Questionnaire (CRSQ)
B. The Addiction Severity Index (ASI) Part A
C. The Addiction Severity Index (ASI) Part B
D. The Demographic Questionnaire
E. The P-CAP Weekly Advocate Time Summary Sheet
F. The Monthly Update Form
G. The Biannual Documentation of Progress
H. The Exit ASI Follow-Up
I. The Client Exit Close-Out Form
J. The Advocate Accounting of Tracing Activity on Missing Post-Exit Client
K. The Lost Post-Exit Client Form

II List of FASD P-CAP Sites

III Informed Consent Forms