a. Recruitment costs, which include the costs of constructing the frame and the relative costs and efficiency of enrolling a participant;

b. Generalizability. What population is being represented?

c. Extent of exposures and other information that can be gathered. By definition, women who enter the study at the birth visit will have more limited data on prenatal exposures than participants enrolled during the prenatal period; while prenatal participants will have less information on prenatal exposures (and much less information on preconception exposures) than the subsequent births to already enrolled mothers or a separate preconception sample.

2. What should be the allocation of sample cases among the various strata? Assume that 10% of the sample is reserved for preconception and special studies; then, the allocation involves the remaining 90,000.

a. One option is the current proposal which is about a 50–50 split or 45,000 participants in each.

b. Another option is something like an 80–20 split allocated between birth and pregnancy, with the pregnancy sample used to form the basis for imputing prenatal exposures (after using medical records for the mothers to get as much prenatal information as possible).

c. Yet another option is like an 80–20 split allocated between pregnancy and birth, with the birth sample used to form the basis for providing generalizability to the data analysis.

d. One extreme could be the entire initial enrollment allocated to the birth stratum, with studies of prenatal and preconception exposures using primarily the subsequent births to originally enrolled mothers.

e. At the other extreme, most of the sample could be allocated to the prenatal stratum with a small birth sample consisting of women who did not receive any prenatal care and are enrolled at the hospital.

3. Given the challenge as stated in the Children's Health Act of 2000 to ''perform complete assessments of environmental influences on children's well-being,'' does the proposed visit schedule and environmental sample collection *(http://www.nationalchildrensstudy.gov/research/workshops/Pages/potential-environmental-exposures-of-interest.pdf)* balance the complex requirements? Specifically comment on the proportion of different types of data collection—primary environmental sample collection, use of biological specimens for biomarkers of exposure, and use of secondary sources including retrospective analysis for environmental exposures. Considerations may include:

a. Are the proposed measures (biomarkers, questionnaires, physical measures) the most appropriate to assess exposures of interest? If not, what measures should be taken?

b. On what decision points should the NCS prioritize exposure assessments?

Some examples of factors to consider are:

1. Potential public health impact of the outcome

2. Technical feasibility including timing of data collection with regard to potential developmental vulnerability

3. Scientific opportunity to address knowledge gaps and illuminate developmental pathways

This RFI is for planning purposes only and should not be construed as a solicitation for applications or proposals and/or as an obligation in any way on the part of the United States Federal government. The Federal government will not pay for the preparation of any information submitted, and/or for the government's use of that information. Additionally, the government cannot guarantee the confidentiality of the information provided.

Dated: February 7, 2013.

Alan E. Guttmacher,

Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Services Accountability Improvement System—(OMB No. 0930–0208)—Extension

This is an extension to the previously OMB approved instrument. The Services Accountability Improvement System (SAIS), which is a real-time, performance management system that captures information on the substance abuse treatment and mental health services delivered in the United States. A wide range of client and program information is captured through SAIS for approximately 600 grantees. Substance abuse treatment facilities submit their data on a monthly and even a weekly basis to ensure that SAIS is an accurate, up-to-date reflection on the scope of services delivered and characteristics of the treatment population. Over 30 reports on grantee performance are readily available on the SAIS Web site. The reports inform staff on the grantees' ability to serve their target populations and meet their client and budget targets. SAIS data allow grantees information that can guide modifications to their service array. Continued approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Act of 1993 (GPRA) reporting requirements that quantify the effects and accomplishments of its discretionary grant programs which are consistent with OMB guidance.

Note that there are no changes to the instrument or the burden hours from the previous OMB submission.

Based on current funding and planned fiscal year 2010 notice of funding announcements (NOFA), the CSAT programs that will use these measures in fiscal years 2013 through 2014 include: the Access to Recovery 2 (ATR2), ATR3, Addictions Treatment for Homeless; Adult Criminal Justice Treatment; Assertive Adolescent Family Treatment; HIV/AIDS Outreach; Office of Juvenile Justice and Delinquency Prevention—Brief Intervention and Referral to Treatment (OJJDP–BIRT); OJJDP-Juvenile Drug Court (OJJDP–JDC); Offender Re-entry Program; Pregnant and Postpartum Women; Recovery Community Services Program—Services; Recovery Oriented Systems of Care; Screening and Brief Intervention and Referral to Treatment (SBIRT), Targeted Capacity Expansion (TCE); TCE/HIV; Treatment Drug Court; and the Youth Offender Reentry Program. SAMHSA uses the performance measures to report on the performance of its discretionary services grant programs. The performance measures information is used by individuals at three different levels: the SAMHSA administrator and staff, the Center administrators and government project officers, and grantees

SAMHSA and its Centers will use the data for annual reporting required by GPRA and for NOMs comparing baseline with discharge and follow-up data. GPRA requires that SAMHSA's report for each fiscal year include actual

results of performance monitoring for the three preceding fiscal years. The additional information collected through this process will allow SAMHSA to report on the results of these performance outcomes as well as be consistent with the specific performance domains that SAMHSA is implementing as the NOMs, to assess the accountability and performance of its discretionary and formula grant programs.

Note that there are no changes to the instrument or the burden hours from the previous OMB submission.

ESTIMATES OF ANNUALIZED HOUR BURDEN [1]—CSAT GPRA CLIENT OUTCOME MEASURES FOR DISCRETIONARY PROGRAMS

Center/form/respondent type	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden	Added burden proportion [2]
Clients:						
Adolescents	3,900	4	15,600	.5	7,800	.34
Adults:						
General non ATR or SBIRT).	28,000	3	84,000	.5	42,000	.34
ATR	53,333	3	159,999	.5	80,000	.34
SBIRT [4] Screening Only	150,618	1	150,618	.13	19,580	0
SBIRT Brief Intervention	27,679	3	83,037	.20	16,607	0
SBIRT Brief Tx & Refer to Tx	9,200	3	27,600	.5	13,800	.34
Client Subtotal	272,730		520,854		179,787	
Data Extract [5] and Upload:						
Adolescent Records	44 grants	44 X 4	176	.18	32	
Adult Records:						
General (non ATR or SBIRT).	528 grants	70 X 3	210	.18	38	
ATR Data Extract	53,333	3	160,000	.16	25,600	
ATR Upload [6]	24 grants	3	160,000	1 hr. per 6,000 records.	27	
SBIRT Screening Only Data Extract.	9 grants	21,517 X 1	21,517	.07	1,506	
SBIRT Brief Intervention Data Extract.	9 grants	3,954 X 3	11,862	.10	1,186	
SBIRT Brief Tx&Refer to Tx Data Extract.	9 grants	1,314 X 3	3,942	.18	710	
SBIRT Upload [7]	7 grants		171,639	1 hr. per 6,000 records.	29	
Data Extract and Upload Subtotal.	53,856		529,382		29,134	
Total	326,586		1,050,236		208,921	

NOTES:

1. This table represents the maximum additional burden if adult respondents, for the discretionary services programs including ATR, provide three sets of responses/data and if CSAT adolescent respondents, provide four sets of responses/data.
2. Added burden proportion is an adjustment reflecting customary and usual business practices programs engage in (e.g., they already collect the data items).
3. Estimate based on 2010 hourly wave of $19.97 for U.S. workforce eligible from the Bureau of Labor Statistics
4. Screening, Brief Intervention, Treatment and Referral (SBIRT) grant program:

* 27,679 Brief Intervention (BI) respondents complete sections A & B of the GPRA instrument, all of these items are asked during a customary and usual intake process resulting in zero burden; and
* 9,200 Brief Treatment (BT) & Referral to Treatment (RT) respondents complete all sections of the GPRA instrument.

5. Data Extract by Grants: Grant burden for capturing customary and usual data.
6. Upload: all 24 ATR grants upload data.
7. Upload: 7 of the 9 SBIRT grants upload data; the other 2 grants conduct direct data entry.

Written comments and recommendations concerning the proposed information collection should be sent by March 21, 2013 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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