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SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. section 300aa-1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The National Vaccine Advisory Committee was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

These are special meetings of the NVAC. Discussions will surround issues related to the Novel Influenza A (H1N1) outbreak. The Committee will discuss the activities and actions of the various HHS agencies and Federal advisory committees that address vaccine issues as it relates to the mission of NVAC. Representatives of State and local health associations will also provide their perspective.

For these special meetings, members of the public are invited to attend by teleconference via a toll-free call-in phone number. The call-in number will be operator assisted to provide members of the public the opportunity to provide comments to the Committee. Public participation and ability to comment will be limited to space and time available. Public comment will be limited to no more than three minutes per speaker. Pre-registration is required for both public attendance and comment. Individuals who plan to attend and need special assistance, such as accommodation for hearing impairment or other reasonable accommodations, should notify the designated contact person at least one week prior to the meeting.

Any members of the public who wish to have printed material distributed to NVAC should submit materials to the Executive Secretary, NVAC, through the contact person listed above prior to close of business one week before each meeting (conference call). A draft agenda and any additional materials will be posted on the NVAC Web site (<http://www.hhs.gov/nvpo/nvac/>) prior to the meeting.

Dated: June 29, 2009.

Bruce Gellin,

*Deputy Assistant Secretary for Health,
Director, National Vaccine Program Office.*
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Cross-community Evaluation of the Native Aspirations Project—NEW

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services (CMHS) will conduct the Cross-Community Evaluation of the Native Aspirations Project. The cross-community evaluation has two tiers. Community-specific activities (Tier 1) are tied to key components of a community plan developed in each participating community that guides program planning and local evaluation through data-driven frameworks and inquiry. Tier I activities will include process and impact evaluation activities to determine the stage of readiness of communities to implement programs,

how accurately community plans reflect the needs and characteristics of each community, how well local resources for American Indian/Alaska Native (AI/AN) youth are mobilized, the experience and impact of the Gathering of Native Americans (GONA), and the impact of the Native Aspirations program on the community. Core cross-community data collection activities (Tier II) are cross-community and include process and impact indicators such as community-level knowledge and awareness of suicide, violence, bullying, and substance abuse; pro-social and help-seeking behaviors among Native youth; and the provision of services specific to Native youth through existing service systems. Tier II activities are directly tied to the primary objectives of the Native Aspirations Project and are designed to augment data collection through the collection of community- and systems-level change measurement. Activities include the Service Provider Focus Groups and the Community Knowledge, Awareness and Behavior Survey (C-KABS).

Data will be collected from Native adults and youth involved in the Community Mobilization Plan (CMP) meeting and the Gathering of Native Americans (GONA), key program stakeholders, Native youth service providers (e.g., teachers, mental health providers, case workers, juvenile justice providers), and other community members (Native youth and adults). Data collection will take place in 25 AI/AN communities across three cohorts. Data collection for the Native Aspirations Cross-community Evaluation will occur over a 3-year period of grant funding for each cohort. Clearance is requested for a 3-year period of data collection that spans FY 2009 through FY 2012 during which Cohorts 3 and 4 will receive 3 years of data collection and Cohort 5 will receive 2 years of data collection with the final year to be submitted in an OMB renewal package. The following describes the specific data collection activities and the 9 data collection instruments to be used, followed by a summary table of respondents and respondent burden.

Community Specific Data Collection Activities—Tier I

- GONA—Baseline Interviews (1 Version). Each participating community will have the opportunity to hold a GONA focused on youth violence, bullying, substance abuse, and suicide concerns. Community GONAs follow four themes that correspond to indigenous values and are core resiliency factors for Native people. These values—belonging, mastery,

interdependence, and generosity—are the framework for this collaborative community event that focuses on individual and community healing, envisioning community wellness, mapping the assets of the community, and committing action in the community toward prevention efforts centered on youth violence, bullying, substance abuse, and suicide. Baseline GONA interviews will be conducted prior to the GONA in each community and will center on the four values and how respondents view and describe their relationships in and with the community; how people in the community deal with youth violence, bullying, substance abuse, and suicide; community members' willingness to work together to address these issues; community protective factors; and suggestions for how community members can work together to address these issues. The GONA baseline interviews will be conducted by telephone in year 1 of grant funding with a maximum of 6 adults per funded community who will attend the GONA in each Cohort. The total number of participants across Cohorts 3, 4 and 5 for 3 years is 150. Items are formatted as open-ended and semi-structured questions. The GONA baseline telephone interviews include 6 items and will take approximately 20 minutes to complete. By using either the GONA Evaluation—Baseline Consent Form, Phone Script or Verbal Consent Form, verbal consent will be received from each respondent prior to administration of the GONA Baseline Interviews.

- **GONA—Followup Interviews (1 Version).** The GONA followup interviews will be conducted several weeks after the GONA in each community. Followup interviews will center around the four values (belonging, master, interdependence, and generosity) and respondents' experience during the GONA; participation in activities; views on community relationships; knowledge of the Native Aspirations Project; knowledge of risk factors for youth violence, bullying, substance abuse, and suicide; community protective factors; willingness of community members to work together and suggestions for working together; and next steps. The GONA follow-up interviews will be conducted in person with a total of 9 adult respondents who attended the GONA in each funded community. Items are formatted as open-ended and semi-structured questions. The GONA followup interviews include 11 questions and will take approximately 60 minutes to complete. These followup

interviews will occur during a site visit in year 1 of each grant for Cohorts 3, 4 and 5. The total number of participants across the three cohorts is 225. Each participant will provide written consent prior to the interview through the GONA Evaluation—Followup Interview Consent Form.

- **GONA—Youth Followup Focus Group Moderator's Guide (1 Version).** The GONA followup focus groups will be conducted several weeks after the GONA with youth who attended the GONA. The focus group moderator's guide follows the same content as the GONA Followup Interviews (see above). Cross-community evaluation staff will conduct up to 2 focus groups with youth in each funded community. Focus groups will consist of a maximum of 9 participants per group and will occur during a site visit in year 1 of each grant for Cohorts 3, 4 and 5. Focus group guides contain 11 items and will last 2 hours. A total of 450 respondents will participate in GONA focus groups. Caregivers will give consent for youth to participate using the GONA FollowUp Youth Focus Group Caregiver Consent form and youth will assent to participate using the GONA FollowUp Youth Focus Group Youth Assent form.

- **Community Plan Focus Group Moderator's Guide (1 Version).** Respondents participating in the Community Plan Focus Groups include youth and adults who attended the Community Mobilization Plan (CMP) meeting in year 1. The guide consists of questions designed to facilitate group communication around the community mobilization planning process, early implementation of the plan, and organizational and community awareness and involvement. Focus group guides contain 7 items and will last 2 hours. The cross-community evaluation team will conduct up to 3 focus groups with a maximum of 9 participants each in year 1 of the grant for each funded community in Cohorts 3, 4 and 5. The total number of participants across cohorts is 675. Consent to participate will be obtained from adult participants through the Community Plan Focus Group Consent form and youths' caregivers will use the Community Plan Focus Group Caregiver Consent form to give consent and youth will assent to participate using the Community Plan Focus Group Youth Assent (Attachment B.6).

- **Community Plan In-depth Interviews (2 Versions).** The Community Plan In-depth Interviews will be conducted in person during year 3 of the grant. The interviews will be conducted with the same individuals who participated in the CMP focus

groups; however, the participants will be divided into two groups with two respective guides. Version 1 will be conducted with participants who remained active in the community mobilization process and Version 2 will be used with respondents who discontinued their involvement with Native Aspirations. The interviews will be used to gather information on the CMP implementation process, organizational and community awareness and involvement with Native Aspirations, and the impact of the Native Aspirations program on the community. The Community Plan In-depth Interview—Version 1 consists of 24 open ended and semi-structured questions and will take 60 minutes to complete. Version 1 will be conducted with up to 9 participants, including Native youth and adults, in year 3 of the grant for a maximum total of 225 respondents across Cohorts 3, 4 and 5. The Community Plan In-depth Interview—Version 2 consists of 11 open ended and semi-structured questions and will take 20 minutes to complete. Up to 9 respondents, including Native youth and adults, will be interviewed using Version 2 in year 3 of the grant. The maximum total of respondents from each funded community across Cohorts 3, 4 and 5 is 225 for Version 2 over the life of the grant. Adult participants for both versions will be required to provide written consent prior to participation using the Community Plan In-Depth Interview V.1 Consent form or the Community Plan In-Depth Interview V.2 Consent and youth participants will need written caregiver consent collected on the Community Plan Interview V.1 & V.2 Caregiver Consent forms and youth assent using the Community Plan Interview V.1 & V.2 Youth Assent forms.

Cross Community Data Collection Activities—Tier II

- **Service Provider Focus Group Moderator's Guide (2 Versions).** The Service Provider Focus Groups are designed to facilitate conversation and information sharing with youth service providers across communities to acquire a broader understanding of provider and service availability for Native youth. Version 1 participants will include agency staff such as teachers, mental health professionals, justice providers and welfare providers and Version 2 participants will include non-agency staff such as paraprofessional providers and/or "natural helpers." However, specific provider types will be identified for each participating community as a function of their existence and number. Version 1 of the

focus group guides consists of 9 items and Version 2 consists of 7 items, each with additional sub-questions/probes covering the availability of wellness and mental health services, how agencies work together, awareness of violence/suicide prevention activities, and areas for improvement. Focus groups will include a maximum of 9 participants per group, with up to 3 focus groups in each community in each of years 1 (baseline) and 3 (follow up) of the grant. Two focus groups will be conducted with agency staff using Version 1, for a maximum total of 900 respondents across the life of the grant. One focus group will be conducted with non-agency staff using Version 2 for a maximum number of 450 participants across the life of the grant for each Cohort. Focus groups will last approximately 2 hours. Written consent will be obtained prior to focus group participation using the Service Provider Focus Group V.1 Consent form and Service Provider Focus Group V.2 Consent form.

- Community Knowledge, Awareness and Behavior Survey (C-KABS)—Adult Version. The C-KABS—Adult Version is designed to gather knowledge and awareness information from adult community members related to suicide, substance abuse, violence, and bullying. In addition, respondents will report on their exposure to Native Aspirations Project activities regarding the prevention of suicide, substance abuse, violence, and bullying. Other constructs include the availability of services, knowledge of youth risk factors, and stigma around and attitude toward seeking services for wellness. The C-KABS—Adult Version will be administered annually, for all 3 years of the grant, to 100 Native adults from each funded community. The survey consists of 36 open and closed-ended questions that include Likert-type agreement scales, prevalence scales and questions, behavior scales and questions, true/false items, and demographic questions. The survey takes approximately 45 minutes to complete. A total of 7,500 respondents will participate from Cohorts 3, 4 and 5. Written consent will be obtained using the C-KABS Adult Consent form.

- Community Knowledge, Awareness, and Behavior Survey (C-KABS)—Youth Version. The C-KABS Youth Version will be administered to youth participants (age 11 and older) to gather information about existing social norms around help-seeking behavior, pro-social behavior (e.g., traditional Indian activities) among youth, and the extent to which respondent youth have been exposed to risky behaviors

(suicide, violence, substance abuse, and/or bullying), as well as their exposure to prevention efforts for risky behaviors related to the Native Aspirations Project. The survey will also contain items about youths' access to pathways to risky behaviors (e.g., how hard/easy is it to get drugs/alcohol), access to and awareness of/willingness to seek help for these behaviors for themselves or others, and youths' engagement in risky and protective behaviors. The C-KABS Youth Version will be administered annually, for all 3 years of the grant, to 100 Native youth from each funded community. The survey consists of 38 open and closed-ended questions that include Likert-type agreement scales, prevalence scales and questions, behavior scales and questions, true/false items, and demographic questions. A total of 7,500 youth will participate from Cohorts 3, 4 and 5. Youths' caregivers will provide consent for youth to participate using the C-KABS Youth Caregiver Consent form and youth will assent to participate using the C-KABS Youth Assent form.

- Community Readiness Assessment (1 Version). The CRA addresses 6 dimensions focused on identified social concern (i.e., youth violence, bullying, and suicide). These dimensions include (a) community prevention efforts, (b) community knowledge of prevention efforts, (c) leadership, (d) community climate, (e) knowledge about the problem, and (f) resources for prevention efforts. In addition, there are 9 developmental levels of readiness within a community that must progress through. CRAs include 26 interview questions which address each of the 6 community readiness dimensions; most items are formatted as open-ended questions with 3 items scored on a scale of 1 to 10. During years 1 and 3, CRAs will be conducted with each funded community in Cohorts 3, 4 and 5 to address youth violence, bullying, and suicide from a multi-faceted perspective. Telephone interviews will be conducted with up to six key informants in the community. Interviews will last 60 minutes and a maximum of 300 respondents will be interviewed. Overall readiness scores will be determined based on key informants' responses and will indicate the community's status with respect to each of these dimensions. Consent will be obtaining using either the Community Readiness Assessment Verbal Consent form or the Community Readiness Assessment Written Consent form.

Data Abstraction and Submission. In addition to the above described data

collection activities, data from existing sources abstracted using the Data Abstraction and Submission Form (i.e., management information systems (MIS), administrative records, case files, etc.) will be analyzed across communities to support the impact stage of Tier I of the cross-community evaluation. To minimize data collection burden on community members, this activity will be tailored to key components identified in the community plan and will be developed around existing data systems and related infrastructures. Cross-community technical assistance providers will assist in the identification of existing data sources and their relevance to locally planned Native Aspirations activities. Data elements may be requested from educational systems, juvenile justice/law enforcement sources, mental health agencies, child welfare, Medicaid, and community organizations (e.g., YMCA, boys and girls clubs, etc.). A maximum of 10 data elements each will be requested from education and juvenile justice/law enforcement sources and a maximum of 5 data elements each will be requested from mental health, child welfare, Medicaid, and community activities. These data will be aggregated from existing data sources, some of which are attendance sheets, management information systems, etc. Grantees are responsible for aggregating these data and submitting them to the Native Aspirations Cross-community Evaluation team by mail, electronic mail, or by uploading the data. The burden associated with accessing, aggregating, and submitting existing data is approximately 6 hours per activity per year. Data abstraction and submission will occur two times per year in each funded community in Cohorts 3, 4 and 5. Seven respondents (one each representing education, juvenile justice, law enforcement, mental health, child welfare, Medicaid, and community activities) in each community will perform data abstraction and submission for a total of 175 respondents and 2,100 hours across 3 years of data collection for Cohorts 3, 4 and 5.

Given the expected variation in available technology (e.g., Internet) and geographic spread of the target populations, flexible implementation options for surveys include local distribution and/or administration of surveys, in-person group, and Internet options and will be determined with each participating community and used when relevant and viable.

The average annual respondent burden is estimated below. The estimate reflects the average annual number of

respondents, the average annual number of responses, the time it will take for each response, and the average annual

burden across 3 years of OMB clearance, which includes 3 years of data

collection for Cohorts 3 and 4 and two years of data collection for Cohort 5.

ANNUALIZED AVERAGES: RESPONDENTS, RESPONSES AND HOURS

Measure name	Number of respondents	Number of responses per respondent	Hours/response	Response burden*
Community Specific Data Collection Activities—Tier I:				
GONA Baseline Interviews	50	1	0.33	17
GONA Followup Interviews	75	1	1.0	75
GONA Youth Followup Focus Groups	150	1	2.0	300
Community Plan Focus Groups	225	1	2.0	450
Community Plan In-depth Interviews—V.1	51	1	1.0	51
Community Plan In-depth Interviews—V.2	51	1	0.33	17
Service Provider Focus Groups—V.1	252	1	2.0	504
Cross Community Data Collection Activities—Tier II:				
Service Provider Focus Groups—V. 2	126	1	2.0	252
C-KABS Adult Version	2,234	1	0.75	1,676
C-KABS Youth Version	2,234	1	0.75	1,676
Community Readiness Assessment1	84	1	1.0	84
Data Abstraction and Submission Form	156	2.0	6.0	1,872
Total	5,688			6,974

* Rounded to the nearest whole number.

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7-1044, One Choke Cherry Road, Rockville, MD 20857 and e-mail her a copy at summer.king@samhsa.hhs.gov. Written comments should be received within 60 days of this notice.

Dated: June 26, 2009.

Elaine Parry,

Director, Office of Program Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day-09-0556]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to omb@cdc.gov. Send written

comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project

Assisted Reproductive Technology (ART) Program Reporting System (0920-0559, exp. 9/30/2009)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The ART program reporting system is used to comply with section 2(a) of Public Law 102-493 (known as the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA)), 42 U.S.C. 263a-1(a)). FCSRCA requires each ART program to annually report to the Secretary through the CDC: the pregnancy success rates achieved by each ART program, the identity of each embryo laboratory used by the ART program, and whether the laboratory is certified or has applied for certification under the Act. The reporting system also makes it possible for the CDC to publish an annual success rate report to Congress as specified by the FCSRCA. This Revision request includes minor wording changes to improve the clarity

of the question concerning pre-implantation genetic diagnosis (PGD), and an increase in the total estimated burden hours due to an increase in the estimated number of responses.

Information is collected electronically through the National ART Surveillance System (NASS), a Web-based interface, or by electronic submission of NASS-compatible files. The NASS includes information about all ART cycles initiated by any of the ART programs practicing in the United States and its territories. The system also collects information about the pregnancy outcome of each cycle as well as a number of data items deemed important to explain variability in success rates across ART programs and individuals.

Respondents are the 483 ART programs in the United States. Approximately 430 programs are expected to report an average of 321 ART cycles each. The burden estimate includes the time for collecting, validating, and reporting the requested information. Information is collected on an annual schedule.

There are no costs to the respondents other than their time. The total estimated annualized burden hours are 89,720.

Estimated Annualized Burden Hours

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
ART Programs	NASS	430	321	39/60