Supporting Statement Part B Healthy Start Evaluation and Quality Improvement OMB Control No. 0915-0338

SUPPORTING STATEMENT PART B: HEALTHY START EVALUATION AND QUALITY IMPROVEMENT, OMB CONTROL NO. 0915-0338

B. Collection of information employing statistical methods

1. Respondent universe and sampling methods

The respondent universe and sampling methods are described below by data collection activity.

Preconception, Pregnancy and Parenting (3Ps) Information Form

For purposes of monitoring, the redesigned Preconception, Pregnancy and Parenting (3Ps) Information Form respondent universe will include all women participating in the Healthy Start (HS) program.

For purposes of the evaluation study, the redesigned 3Ps Information Forms' respondent universe will include all women enrolling in HS case management services across all 100 HS grantees during the study period. The client data is the primary data source for the utilization and outcome evaluations. The client data provides data on individual-level socio-demographics, service needs, services received, and follow-up visits and enables DHSPS to understand the HS population and to track outcomes and progress at the participant level. The redesigned 3Ps Information Forms are divided into six tools, including a Demographic Intake Form, and assessments of key reproductive phases, including Pregnancy Status/History, Preconception, Prenatal, Postpartum, and Interconception/Parenting. They also facilitate aggregate or crude benchmarking and comparison with national databases on various health behaviors, health services received, and perinatal outcomes.

We expect an overall response rate of at least 80 percent for Healthy Start participants completing the redesigned 3Ps Information Forms. Although response to these Forms is part of the process for enrollment and annual monitoring for all participants in HS case management services, we anticipate that some participants will decline to complete the screening forms due to the sensitive nature of the questions. Therefore, the anticipated sample size is 32,540 women across all Healthy Start projects (80% of the estimated 40,675 participants in HS case management services).

All 100 HS grantees will provide the required linkage variables (Table B.1) for each pregnant and postpartum HS participant with a known or expected delivery during the evaluation study period. The Vital Records Offices (VROs) in each state will complete the linkage of HS participants to birth certificates and will then transfer the data to HRSA/MCHB without personally identifiable information for all linked HS participants and non-participants in the same county/city to facilitate analytic comparison. These data will include birth certificate data on linked participants with client ID number, date of enrollment as well as birth certificate data for non-participant controls from the same city or county with geographic identifiers (census tract or zip code). HRSA/MCHB will use the unique client ID to link the vital records data to the redesigned 3Ps Information forms and identify the services received by HS participants, which will allow the evaluation team to fully assess the type, dose and frequency of services HS participants received and the impact these services had on important benchmark and outcome

measures (Attachment D). Finally, the VROs will update the linkage of HS participants and controls to include any subsequent infant death certificates and send the linked data file to HRSA/MCHB.

Table B.1 Individual Identifiers for Vital Records Linkage

Linkage variables
Mother's name
Mother's date of birth
Mother's address at time of delivery
Mother's social security number
Mother's race
Mother's ethnicity
Mother's Medicaid status
Mother's gravidity
Mother's parity
Mother's date of enrollment
Mother's Unique Client ID #
Infant date of birth (or expected month or date of
delivery if known)
Infant birth hospital
Infant sex
Infant name
Infant birthweight

Bold = required elements

The sampling method for the PRAMS oversampling component of the HS evaluation is derived from the 86 HS grantees located in states that conduct the PRAMS survey. To improve the chances of evaluating an operational HS program early in the grant cycle, the PRAMS oversampling was restricted to continuing grantees (75 of 100 total grantees). Similarly, CDC PRAMS recommended restricting the sample to grantees in states which currently field PRAMS (n=40) given the potential lack of capacity in new PRAMS Phase 8 states (up to 61 states/jurisdictions/tribes). Therefore, the HS Sampling Frame for the PRAMS oversampling included 63 of 75 continuing grantees that are located in current PRAMS states.

Based on available funding and CDC support services, it was determined that 15 HS grantees could be selected for PRAMS oversampling. To ensure scientific integrity, the 15 HS grantees were randomly selected within strata determined to be of importance to the program. The strata include cells categorized by Grantee Level (1, 2, 3)¹, Service Area Focus (Urban, Rural, Border, AI/AN), and Region (Midwest, Northeast, South, West). Within the sampling frame, there were only 3 grantees located in the Western Region (all Level 1 grantees in NM and OR). Given that

¹ Level 1 Community-based HS programs serve a minimum of 500 participants per year and implement activities under the five approaches; Level 2 Enhanced Services grantees serve a minimum of 800 participants and engage in Level 1 activities as well as activities to stimulate community collaboration; Level 3 Leadership and Mentoring HS grantees serve a minimum 1,000 participants and engage in activities under Level 1 and 2, as well as activities to expand maternal and women's health services, develop place-based initiatives, and serve as centers to support other HS and similar programs.

most Western HS grantees are Urban (7 of 12), a Western Urban Level-1 grantee was selected with certainty. To ensure geographic representation of the remaining regions, Level-2 and Level-3 grantees were selected in the general proportion of these grantees by region.

Beginning in fall 2016, 15 randomly selected HS grantees will send linkage variables (Table B.1) for pregnant and postpartum HS participants to their state/jurisdiction VROs. The VROs will link to the birth certificate and note which individuals are HS participants. PRAMS offices in the randomly selected states will sample these individuals to take part in the PRAMS survey (2 to 9 months postpartum). Oversampling via PRAMS will require ongoing monthly linkage to identify HS participants for monthly batch sampling. The CDC will provide HRSA/MCHB with the full PRAMS file of all PRAMS participants in the selected states (both HS participants and non-participants), including linked vital records and geographic identifiers for analytic purposes. State/jurisdiction VROs will then transfer any subsequent infant death certificate data for the PRAMS sample to HRSA/MCHB. Finally, HRSA/MCHB will link client-level program information on service receipt within HS to PRAMS and vital records data, using the client ID number, to complete evaluation analyses. This will allow the evaluation team to fully assess the type, dose and frequency of services HS participants received and the impact these services had on important benchmark and outcome measures. Further, oversampling via PRAMS will enable comparisons between HS participants and non-participants. Specifically, the outcome evaluation will employ a quasi-experimental method, which will include two types of comparisons:

- 1. A matched individual comparison analysis of linked vital records for HS participants and non-participants in the same general geographic service area for all 100 HS grantees, which maximizes generalizability and will allow for assessment of the key outcome of interest, infant mortality, with adequate statistical power.
- 2. A matched individual comparison analysis of HS participants and non-participants by oversampling of the Pregnancy Risk Assessment and Monitoring Survey (PRAMS) for a random sample of 15 HS grantees. This component of the evaluation data collection strategy will maximize internal validity with a broader set of outcomes and control or matching characteristics that can influence selection into the program.

National Healthy Start Program Survey (NHSPS)

All Healthy Start projects will be asked to complete the NHSPS to ensure that consistent information is collected about implementation across the program and to enable analysis of variation in implementation to contribute to implementation and utilization studies. One-hundred Healthy Start projects are funded for the grant period of June 2014 to May 2019. Project directors are likely to take the lead on responding to the survey but may delegate sections of the survey to other project staff.

Community Action Network (CAN) survey

In each of the 15 Healthy Start projects selected for the PRAMS oversampling, the survey will be fielded with CAN board members and committee chairs—approximately 10–15 per project for a total of 225 across the projects. Healthy Start projects will be asked to give a list of CAN board and committee members and their contact information. If there are more than 15 per

site, we will randomly select up to 15 members. Individual consumers, community leaders, or those not associated with an organization will not be included in the respondent universe because the purpose of this data collection is to gauge organizational relationships in the community. Healthy Start participant perspectives will be captured in the focus groups, and community leader perspectives may be captured during the site visits.

Healthy Start Site Visits

The site visits will be conducted in the 15 Healthy Start communities selected for the PRAMS oversampling. During the site visits, four to seven key informant interviews will be conducted with Healthy Start administrative staff (one interview per site visit), Healthy Start service staff (one to two interviews per site visit), health care providers (one to two interviews per site visit); we expect on average six interviews per site for a total of 90 interview across 15 sites. The number of key informant interviews that can be scheduled within the allotted time will depend on logistics for scheduling the focus groups (which will occur during the same two-day site visit) and the amount of travel time required between interviews.

The project director at each Healthy Start site will be asked to identify service staff members and providers who have regular interactions with Healthy Start participants as well as active CAN members. We expect these Healthy Start service staff members will include outreach workers, case managers, and health educators. Providers may include clinicians, such as physicians, midwives, and nurse practitioners. CAN members will include representatives of local organizations in the community with an interest in improving maternal and child health.

Healthy Start Focus Groups

The Healthy Start focus groups will be conducted in the 15 Healthy Start projects selected for the PRAMS oversampling. One focus group will be conducted in each community, with 10 to 12 Healthy Start participants per group. Therefore, the focus groups will include a total of 150 to 180 participants across the 15 projects. Based on our experiences conducting focus groups with similar populations of low-income women, we anticipate recruiting twice the number of women to obtain the necessary numbers for the focus groups. The recruitment strategy will rely on assistance from the 15 Healthy Start projects in posting information and handing out flyers about the focus groups to their participants. The recruitment materials will invite interested focus group participants to call a toll-free number, and those who are eligible will be given information about the dates and locations of the focus groups. Eligible participants include women with at least one live birth while enrolled in Healthy Start that are active participants at any of the 15 selected Healthy Start projects (that is, receiving services on an ongoing basis). A reminder telephone call and/or email will be sent to participants one week in advance and again the day before the focus group.

2. Procedures for the collection of information

Redesigned 3Ps Information Forms

Healthy Start projects will collect information using the redesigned 3Ps Information Forms as part of their project monitoring and evaluation activities.

- Monitoring. Women will be enrolled on a rolling basis over the remainder of the five-year grant period for Healthy Start projects. Once women consent to participate in the Healthy Start program, they will be administered the relevant redesigned 3Ps Information Forms (demographics, pregnancy status, prenatal, postpartum, etc.) at enrollment and then as appropriate thereafter. See Attachment K for contact script.
- Evaluation. Information on Healthy Start women will be drawn from the redesigned 3Ps Information Forms for the evaluation, and will be linked to vital records data and (for participants in the 15 randomly selected HS/PRAMS sites) PRAMS survey data. Data will be abstracted for Healthy Start women who were pregnant or postpartum (less than two years) and enrolled in HS case management services during the study period. Non-HS participant controls will not complete the redesigned 3Ps Information Forms. Comparisons to HS participants will be based on vital records and PRAMS survey data only.

For both monitoring and evaluation, the form will be administered using a web-based application at many of the grantee sites while some programs will collect the data elements using paper forms. Further, some forms are self-administered while others are administered by program staff. Grantees requiring a paper form may use PDF forms modeled after the redesigned 3Ps Information forms. Grantees using the PDF forms may save these forms locally and can complete them for clients on a laptop or other device in the field, saving them for upload later when an internet connection is available. Both the web-based and PDF formats will reduce burden on administering staff and women participants and improve data quality by allowing the collection of information that is specific to each respondent and having automated quality checks. In order to increase compliance, HS participants are sent a written reminder of their scheduled visit date, time, and location via email and/or contacted by telephone, along with procedures to follow if their appointment needs to be canceled or rescheduled.

National Healthy Start Program Survey

The National Healthy Start Program Survey will be conducted with all Healthy Start grantees over a two-month period at the end of the second and fourth grant years. The survey is designed to be self-administered through a web-based application by Healthy Start staff. The web-based application will allow respondents to stop and save the survey and return to it later, reducing burden as they may complete it at their convenience. In addition, internal skip patterns and range checks will be programmed into the survey to ensure the accuracy of data and that respondents do not answer questions unnecessarily. All Healthy Start project directors will be emailed a link to the survey for completion as well as accompanying material, such as a frequently asked questions document. Once they complete the survey, they will click on a submit button and HRSA will be informed that the grantee completed the survey. The web-based application will flag incomplete surveys weekly and grantees will receive email reminders to complete the survey.

Community Action Network Survey

The CAN Survey will be conducted over a two-month period with up to 15 CAN board members and committee chairs at 15 Healthy Start sites selected for PRAMS oversampling at the end of the third and fifth grant years. There are approximately 10 to 15 CAN board members and committee chairs per Healthy Start grantee for a total of 225 respondents. The survey is designed

to be self-administered through a web-based application by CAN members. The survey will take approximately 30 to 45 minutes to complete. The web-based application will allow respondents to stop, save the survey, and return to it at a later time, thus reducing burden as they may complete it at their convenience. In addition, internal skip patterns and range checks will be programmed into the survey to ensure the accuracy of data and that respondents do not answer questions unnecessarily. Active CAN members will be emailed a link to the survey for completion as well as accompanying material, such as a frequently asked questions document. Once CAN members complete the survey, they will click on a submit button and HRSA will be informed that the CAN member completed the survey. The web-based application will flag incomplete surveys weekly, and CAN members will receive email reminders to complete the survey.

Healthy Start Site Visits

Site visits will be conducted with 15 Healthy Start grantees selected for PRAMS oversampling. At each site visit, we will schedule meetings to conduct interviews with four types of key informants: Healthy Start administrative staff, Healthy Start service staff, partner health care providers, and CAN participants. All interviews will be in person. Interviews with Healthy Start administrative staff will last up to 75 minutes, with one conducted per site. Up to two 45-minute interviews will be conducted with service staff, such as outreach workers, case managers, and health educators. Up to two 30-minute interviews will also be conducted with individual health care providers that serve Healthy Start participants in the community, and up to two 45-minute interviews will be conducted with individual active CAN members. We anticipate an average of six interviews per site for a total of 90 interviews across the 15 selected Healthy Start sites. At each site, we will attempt to schedule interviews to take place over two days and within regular work hours. The two-person interview team will include a senior team member to lead the interviews and a junior member to help schedule and facilitate the interviews. We will audio-record the interviews, if key informants agree, and transcribe the recordings.

Healthy Start Focus Groups

One focus group will be conducted in each of the 15 Healthy Start grantees selected for PRAMS oversampling, with 10 to 12 women per group, for a total of 150 to 180 participants. The groups will be conducted in an accessible location, such as Healthy Start offices, public libraries, or community centers. We will ensure that the space is private (such as an enclosed conference room) to maintain privacy and minimize distractions. In each site, we plan to schedule the focus group based on participants' preferences as stated during the time of recruitment. Each focus group will last a total of 90 minutes. Fifteen minutes will be devoted to intake (including obtaining consent), welcome, and introductions; 60 minutes to discussion; and 15 minutes to wrap up the session and distribute the gift cards. The focus groups will be taped for transcription. Upon arriving, participants will receive a participant information form to collect demographic information and responses to closed-ended questions about their perinatal experiences. After completing the focus group, women will receive a \$25 gift card for their participation. Each focus group will be staffed with a moderator and facilitator. The facilitator will be responsible for intake, processing gift cards, welcoming late arrivals, recording the discussion, and taking notes. The moderator will lead the group discussion, ensuring that all participants have an opportunity to speak, drawing out those who are reticent, and cueing participants to share the diversity and similarity of their experiences.

Information collection schedule

Table B.2 summarizes the information collection schedule. After OMB approval is received, enrollment and consent procedures will be adapted as needed for each site, and Healthy Start staff will be trained on how to implement the enrollment and consent procedures for the redesigned 3Ps Information Forms. Upon completion of the training, staff will begin enrolling eligible women using the materials described above. Information collection from women will begin in October 2016 for Healthy Start grantees and continue until the end of the grant in May 2019. HRSA will conduct data quality reviews periodically during the field period. The NHSPS will be sent out for completion in March to April 2016 and March to April 2018 and the CAN Survey will be sent out for completion during April to May 2017, and April to May 2019. The Healthy Start site visits and focus groups will occur during January to April 2019. Attachment B1-B6 consists of the redesigned 3Ps Information Forms; Attachment E consists of the NHSPS; Attachment F consists of the CAN Survey; Attachment G consists of the site visit protocols; and Attachment H consists of the focus group protocols.

Table B.2. Information collection schedule

Task	Time Schedule
Develop/Establish Data Collection Systems	
Award contract for HS Monitoring and Evaluation Data System (to support the redesigned 3Ps Information Forms)	September 2015
Establish IAA with CDC NCHS to receive 2017 vital records data for HS participants and non-participants residing in cities/counties from 37 states and DC	November 2015
Award contract to support implementation of the evaluation plan	September 2016
Train HS grantees on the HS Monitoring and Evaluation Data System and redesigned 3Ps Information Forms	–October - November 2016
Administer the National Healthy Start Program Survey (NHSPS)	
Administer the NHSPS to grantees (Round 1)	March – April 2016
Analyze preliminary survey data	August 2016
Prepare report and brief stakeholders	August/September 2016
Administer the NHSPS to grantees (Round 2)	March – April 2018
Analyze preliminary survey data	June 2018
Prepare report and brief stakeholders	August 2018
Administer the CAN Survey	
Administer the CAN Survey	March - April 2017
Analyze preliminary survey data	June – August 2017
Prepare report and brief stakeholders	September 2017
Administer the CAN Survey (Round 2)	March–April 2019
Analyze preliminary survey data	June-August 2019

Prepare report and brief stakeholders	September 2019
HS Participant Linkage to Vital Records and PRAMS	
Begin data collection using the HS Monitoring and Evaluation Data System (HSMED) and/or PDF forms	October 2016
Establish linking protocol(s) between HS grantees and Vital Record Offices	July - September 2016
State/jurisdiction Vital Record offices receive funds to link HS participants to vital records	September 2016
HS grantees participating in PRAMS oversample begin sending individual identifiers (monthly) to state/jurisdiction Vital Record offices	March 2017- February 2018
All HS grantees provide individual identifiers to state/jurisdiction Vital Record offices for annual linkage (CY 2017)	April 2018
State/jurisdiction Vital Record offices link HS participant data to birth records (monthly) using unique client-id (for grantees participating in PRAMS oversample)	March 2017 – February 2018 (for CY 2017 births)
State/jurisdiction Vital Record offices link HS participant data to birth records (annually) using unique client-id (for all grantees)	May 2018
State/jurisdiction Vital Record offices link HS participant data to death records (monthly) using unique client-id (for grantees participating in PRAMS oversample)	May 2019
State/jurisdiction Vital Record offices link HS participant data to death records (annually) using unique client-id (for all grantees)	May 2019
State/jurisdiction Vital Records offices provide linked CY 2017 birth data to MCHB/HRSA	September 2018
State/jurisdiction Vital Records offices provide linked CY 2018 infant death data to MCHB/HRSA	September 2019
Develop protocol to transfer PRAMS data to MCHB/HRSA	May/June 2018
Selected PRAMS programs receive funding for oversampling	September 2016
PRAMS Phase 8 data collection – identified HS participants will be surveyed for birth during CY 2017	April 2017-March 2018
Transfer PRAMS data file for all participants in selected states and HS-linked participants	September 2018
Conduct Site Visits	January-April 2019
Conduct Focus Groups	<mark>January-April</mark>

	<mark>2019</mark>
Conduct Analysis and Reporting	
Conduct comparison analyses using vital records and PRAMS data for HS participants and non-participants	May 2018 (births) and May 2019 (deaths)
Prepare final study report and brief stakeholders	December 2019

3. Methods to Maximize Response Rates and Deal with Nonresponse

Redesigned 3Ps Information Forms

The data collection procedures discussed below were designed to maximize response rates and to promote the accuracy and completeness of information collected.

Training Grantees. Prior to the launch of data collection, grantees will be briefed and trained to ensure they have a full understanding of the informed consent procedures for adults and minors that comprise enrollment and the data collection plan. HRSA will provide technical assistance to each organization to use procedures customized to its staffing arrangement and work flow as needed. This will ensure that all consent procedures are clear and implementable at the site level. Well-trained staff will help improve response rates by gaining consent, by administering the form in a professional but friendly manner that keeps the respondent actively engaged in the interview, and ensuring complete information is collected. The training will be based on a detailed manual and supplemented by practice exercises in gaining cooperation and multiple practice exercises to help staff administering the form become comfortable with the various major paths of the form. During the training, problems with language or routing are sometimes identified. HRSA will leave sufficient time between training and the start of interviewing to correct and test any errors discovered during training.

Implementing the Form in a Web-Based Application. Implementing the form in a web-based application will provide a controlled way to collect data that ensures high quality and consistency by enforcement of rules to avoid various kinds of error. The application will (1) control the routing through the form, thus avoiding pathing errors; (2) control response ranges so that out-of-range values are checked and updated in real time by staff; and (3) make consistency checks to ensure that the respondent's answers are consistent throughout the questionnaire. In addition, the application will fill responses from previously asked questions, thus helping staff smoothly administer the survey.

Review of the Submitted Forms to Ensure High Quality Data. Monitoring how staff administer the form, especially early in the process, is critical to ensuring the high quality of the data. During the first week of the launch of data collection, HRSA will review and debrief the first cases completed by each staff. After this point, HRSA may periodically monitor administration through submitted cases. The review will focus on identifying missing and inconsistent information to provide corrective feedback.

Debriefing Interviewers to Identify Problems Early. HRSA regards debriefing staff as a critical step in quality control of the data collection. Staff will be debriefed after the first few

weeks of data collection to identify problems in the question language or survey routing. Corrections will be made to errors identified during the debriefings. Periodically, HRSA will update the training manual to keep pace with changes to or clarifications of procedures, thus ensuring consistency across all staff.

Reviewing Data Frequencies. Frequency reviews are an important tool in ensuring data quality. To determine whether the instrument is performing as specified, frequencies will be reviewed after the first 50 forms are submitted. If programming errors are detected (for example, erroneous skip logic or inadequate range specifications), HRSA will correct the errors immediately. If missing data need to be retrieved from respondents, staff will be instructed to follow up and obtain the information.

Minimizing Nonresponse Bias. A previous Healthy Start participant survey had a response rate of 66 percent.² Based on that experience we are aiming for a response rate at Healthy Start sites of 80 percent. We anticipate an increased response rate because we will use a mixed methods approach that includes contacting participants via email to complete data collection forms, providing opportunities to complete forms at the grantee site and/or during home visits, and following up with non-responding participants via phone to complete the data collection forms. Previous administrations of the forms only included a telephone-based approach.

The potential degree of nonresponse bias is a function of both response rate and how different respondents and non-respondents are with respect to factors that are related to the outcomes (for example, if non-respondents are less likely to have access to nutritious foods, they could have worse birth outcomes than the respondents, making the comparison group look better than the population as a whole). We will do everything possible to maximize the response rate.

National Healthy Start Program Survey (NHSPS) and Community Action Network (CAN) survey

Two previous Healthy Start Program Surveys have been conducted with grantees (OMB #0915-0287 and #0915–0338), with a response rate of 99 and 100 percent. Based on previous experiences conducting Network Surveys with organization partners, we expect a response rate between 80 and 95 percent for the CAN survey. Although we do not expect issues with responses, the self-administered web-based NHSPS and CAN surveys will allow programs to stop and return to the survey at their convenience, encouraging completion. In addition, clear instructions with an email and telephone number for a help desk will be provided to answer any questions that respondents may have. Implementing the form in a web-based application will provide a way to collect high quality and consistent data and minimize burden by: (1) routing respondents through the form, thus avoiding pathing errors; (2) including range checks so that out-of-range values are checked and flagged for respondents to correct immediately; and (3) including consistency checks to ensure that the respondent's answers are consistent throughout the questionnaire. In addition, the application will fill responses from previously asked questions, thus helping respondents smoothly complete the survey. We will develop clear instructions and program the web-based application to be as intuitive as possible to minimize time that grantee

² Rosenbach, M., S. O'Neil, B. Cook, L. Trebino, and D. Klein Walker. "Characteristics, Access, Utilization, Satisfaction, and Outcomes of Healthy Start Participants in Eight Sites." *Maternal and Child Health Journal*, 2010, 14(5):666–79.

staff and CAN member staff have to be trained. During the field period, the web-based application will automatically send weekly reminders to those that have not completed the survey.

Healthy Start Site Visits and Focus Groups

Response to the two qualitative components—site visits and focus groups—is expected to be high because of the interest of Healthy Start projects in the evaluation among stakeholders and Healthy Start grantees' ability to leverage their relationships with participants for focus group recruitment. For the site visits, interviews will be scheduled at the convenience of the key informant. A response rate of 95 percent is expected for key informants during the site visits based on experience with similar activities and a typically high level of motivation from the Healthy Start staff and their partners. Outreach to prospective focus group participants will take place through Healthy Start grantees; we will ask Healthy Start grantees to post flyers and other materials about the focus groups in their location and mention the focus groups to their participants. Even with Healthy Start endorsement of the focus groups to their participants, we expect a 50 percent rate of no-shows on the day of the focus group based on experiences conducting focus groups with similar populations of Medicaid and CHIP participants and pregnant and postpartum women for the Text4baby evaluation. Therefore, we will recruit twice the target number of focus group participants. We will also offer an incentive of \$25 in the form of a gift card for their time. In addition, the groups will be scheduled based on the preferences of the most women as provided by them at the time of recruitment. The groups will be held in convenient locations to increase attendance. Reminders will be sent to confirmed participants by email and/or telephone one week in advance and again the day before the group.

4. Tests of procedures or methods to be undertaken

HRSA carried out a pilot test of the redesigned 3Ps Information Forms with 9 Healthy Start participants; the NHSPS with two Healthy Start programs; and the CAN Survey with five CAN members. Key findings for each instrument are discussed below. Attachments J1 and J2 contain the Pilot Test Report and Recommendations for the redesigned 3Ps Information Form, and the NHSPS and CAN Survey.

Redesigned 3Ps Information Forms. The timing of the redesigned 3Ps Information Forms was shorter than the original estimates. Table B.3 below provides the new time estimates for each form.

Table B.3. Revised Time Estimates for Redesigned 3Ps Information Form Based on Pilot Test

Form Name	Average Burden per Response (in hours) Pre Pilot Test	Average Burden per Response (in hours) Post Pilot Test
3Ps Information Form: 1. Demographic Intake Form	<mark>0.25</mark>	<mark>0.08</mark>
2. Pregnancy Status/History	0.42	0.17

3. Preconception	<mark>1.5</mark>	<mark>1.00</mark>
4. Prenatal	<mark>2.00</mark>	<mark>1.00</mark>
Postpartum	<mark>1.8</mark>	<mark>1.00</mark>
6. Interconception/	2.00	1.00
Parenting	<mark>∠.00</mark>	1.00

Additionally, a net total of 11 core questions were deleted from the screening tools and several were revised. The most commonly noted issues were related to questions that were medical/clinical in nature, such as questions about medications and immunizations, and/or too intrusive. An introductory paragraph was added to each tool outlining the purpose of the questionnaire. Several revisions were recommended to improve the clarity, flow and timing of the questions in the screening tools. The revisions will improve respondent comprehension and ease of staff administration of the tools. Two substantial changes were recommended to the Parenting/Interconception Tool: (1) a question (and resultant skip pattern) for identifying mothers who may have experienced the death of their infant after the Postpartum Tool; and (2) a question to identify participants who could be in the parenting phase with a young child and also be pregnant.

NHSPS. The timing of the survey was an average of three hours, which was shorter than the instrument used for the previous evaluation (four hours). However, to further reduce burden, we pared down the survey to an estimated burden of two hours. Based on feedback from the pre-test, we revised questions to improve flow and reduce burden, such as combining questions related to outreach and participant recruitment strategies and changing requests for number of participants to response options for percentage ranges. We added a few additional topics on domestic violence and immigration for one question. Additionally, we eliminated or simplified questions for which project applications and reports may be a source of information, such as additional names for the project in the community, specific models and curricula used, average case load, and specific types of activities engaged in related to health insurance enrollment; many of these questions were open-ended responses or required a series of responses that require more time to complete. We found that grantees went through and checked all topics asking about their provision of health education for a specific topic as if they may not have fully read each topic. Because the list was very long, we deleted health education topics already covered under the participant-level form to minimize the length of the list and encourage more-thoughtful responses. Otherwise, we made minor wording changes to make questions and response options more clear.

CAN Survey. The timing of the survey was consistent with the budgeted survey length (45 minutes). The survey worked well but needed a few additional instructions for questions related to estimating numbers and dates, and a few additional "don't know" response options were added. We also deleted one question that asked for budget information and the fields where CAN members could list organizations outside of the CAN with which they collaborated; these questions were confusing for all respondents and yielded unreliable data. As key community organizations are represented on the CAN, we anticipate that this will not affect the quality of the information collected.

5. <u>Individuals consulted on statistical aspects and individuals collecting and/or analyzing data</u>

Individuals consulted on statistical aspects

HRSA/MCHB staff and leadership, an evaluation Technical Expert Panel, and the Healthy Start CoIIN (Collaborative Improvement and Innovation Network) grantees were consulted about the substantive, methodological, and statistical aspects of the study. Their recommendations were incorporated into the study design and instruments on an ongoing basis. The person responsible for receiving and approving the instruments and information collection is Jamelle Banks, MCHB. Table B.4 lists the individuals consulted.

Table B.4. Individuals consulted

Name	Affiliation Affiliation
Hani K. Atrash MD, MPH (designed data collection)	Director, Division of Healthy Start and Perinatal Services Maternal and Child Health Bureau Health Resources and Services Administration 5600 Fishers Lane, Room 18N29, Rockville, MD 20857 hatrash@hrsa.gov tel: 301-443-0543 fax (301) 594-0878
Jamelle E. Banks, MPH (design data collection and will approve contract deliverables from yet-to-be- awarded contractor)	Chief Evaluation Officer Division of Epidemiology Office of Epidemiology and Research Maternal and Child Health Bureau Health Resources and Services Administration 5600 Fishers Lane, Rm 18N118, Rockville, MD 20857 jbanks@hrsa.gov tel: 301-443-1726 fax: 301-480-0508
Gwendolyn Daniels (designed data collection)	Institute for Population Health Detroit, MI 313-324-9717 gdaniels@ipophealth.org
David De la Cruz, PhD, MPH (designed data collection and approves deliverables from JSI, a contractor)	Captain, US Public Health Service Deputy Director Division of Healthy Start and Perinatal Services Maternal and Child Health Bureau Health Resources and Service Administration Department of Health and Human Services 5600 Fishers Lane Room 18N-25 Rockville, MD 20857 (301) 443-0543 David.delaCruz@hrsa.hhs.gov

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Individuals collecting and/or analyzing data

Funded Healthy Start grantees and HRSA/MCHB contractor staff at all 100 grantee sites will collect data for the redesigned 3Ps Information Forms. A list of funded Healthy Start grantees is posted at http://www.hrsa.gov. An evaluation contractor (see Statement of Work in Attachment L) will be selected to collect information for the evaluation. The evaluation contractor will also assist HRSA/MCHB's Office of Epidemiology and Research with analysis of the data collected for all five information collection efforts presented in this OMB package.