Maternal and Infant Home Visiting Program Evaluation (MIHOPE)

OMB Information Collection Request
0970 - 0402

Supporting Statement

Part A

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Submitted By:
Office of Planning, Research and Evaluation
Administration for Children and Families
U.S. Department of Health and Human Services

7th Floor, West Aerospace Building
370 L'Enfant Promenade, SW
Washington, D.C. 20447

Project Officer:
Lauren Supplee

Part A. JUSTIFICATION

A1. Circumstances necessitating data collection

In 2011, the Administration for Children and Families (ACF) and Health Resources and Services Administration (HRSA) within the U.S. Department of Health and Human Services (HHS) launched the Mother and Infant Home Visiting Program Evaluation (MIHOPE). This evaluation, mandated by the Affordable Care Act (ACA), will provide information about the effectiveness of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) program in its first few years of operation, and provide information to help states and others develop and strengthen home visiting programs in the future. It will attempt to fill gaps in research that were identified in recent reviews of home visiting programs funded by the U.S. Department of Health and Human Services through the Home Visiting Evidence of Effectiveness (HomVEE) project. The evaluation is being conducted by MDRC in partnership with Mathematica Policy Research, James Bell Associates, Johns Hopkins University, and the University of Georgia.

The proposed evaluation will be conducted in approximately 85 sites across approximately 12 states. In each site, approximately 60 families will be randomly assigned to either MIECHV-funded home visiting or to a control group, which will be given referrals to other services in the community. Families will be eligible for the study if they include a pregnant woman or an infant under six months old and the mother is at least 15 years old. The goals of the evaluation are: (1) to understand the effects of home visiting programs on parent and child outcomes, both overall and for key subgroups of families, (2) to understand how home visiting programs are implemented and how implementation varies across programs, and (3) to understand which features of local home visiting programs are associated with larger or smaller program impacts.

MIHOPE includes two phases. Phase 1 includes site recruitment, recruitment of families and collection of baseline data on families, and the collection of data on program implementation. Phase 2 includes follow-up data collection, including a survey conducted with parents around the time the child is 15 months old, observations of interactions between parents and children, observations of the home environment, direct observations of child development, direct measurement of maternal weight and child height and weight, and continuing collection of information on program implementation. In addition, there is a possibility that saliva would be collected to measure cotinine and cortisol. If so, a request for a nonsubstantive change request will be submitted.

OMB approved a data collection package for Phase 1 in July 2012. This document provides support for the data collection efforts of Phase 2.

A2. Purpose and use of the information collection: How, by whom, and for what purpose the information is to be used.

Phase 1 of the evaluation includes three broad sets of data collection activities, which were previously approved by OMB. These are summarized below:

1. Collect information from state MIECHV administrators and local programs to inform the selection of states and sites for the evaluation. The overall goal of site recruitment in MIHOPE is to select approximately 85 sites across approximately 12 states.
2. Recruit families into the study and collect baseline information on families using a one-hour telephone survey.
3. Collect information on the implementation of home visiting programs. Information on program implementation comes from surveys of home visitors, home visitor supervisors, home visiting program managers; semi-structured interviews with MIECHV administrators; surveys of administrators of other programs serving the same communities as those served by evaluation sites; logs maintained by supervisors and home visitors; and semi-structured interviews with home visiting program staff at evaluation sites.

Phase 2 of the evaluation will include the following activities (more detailed information for each activity follows this list):

1. Collect information on participating families through a one-hour telephone survey when the child is approximately 15 months old. The follow-up survey will provide information on each domain specified for evaluation in the ACA.
2. Conduct direct observations of parent-child interactions using the three bags task, which is intended to capture the parenting constructs of parental sensitivity, cognitive stimulation, positive regard, intrusiveness, negative regard, detachment, relationship quality (degree of relatedness and mutual engagement), and boundary dissolution (parent's inability to maintain an appropriate role in his or her interaction with child). From this task, children's behaviors towards the parent will also be gathered in the context of the parent-child interaction, including engagement with the parent, sustained attention, and negativity towards the parent. In addition, the parent and child dyad will be observed in a "cleaning up" task in which they are asked to clean up the objects from the three bags task. The clean-up task will be used to assess parent's use of guidance and control strategies, as well as the child's compliance.
3. Administer the Preschool Language Scales, Fifth Edition (PLS-5), Auditory Comprehension scale to assess the child's ability to be attentive and respond to stimuli in the environment and to comprehend basic vocabulary or gestures at 15 months.
4. Measure the child's weight and height to provide information on whether the child's growth is within a normal range or exhibits early signs of underweight or obesity. In addition, measure the mother's weight to assess the effects of home visiting on maternal weight and obesity.
5. Continue to collect information on the implementation of home visiting programs through weekly logs completed by home visitors. Data on program implementation will be used to describe how home visiting programs are organized and operated, how services are related to staff and family characteristics, and how features of local programs are related to impacts of local programs. Logs maintained by home visitors will be collected through June 2016 or until the child is no longer in the home visiting program. Weekly logs provide information on how often home visits are conducted and the content of the visits. The log submitted with this package have been updated slightly from the version approved by OMB during Phase 1 of MIHOPE. If home

visitor logs need to be collected beyond the expiration date of this OMB clearance, a request for information collection extension will be submitted.

6. Possibly, collect saliva from the parent and child for purposes of measuring cotinine and cortisol. Cotinine is an indicator of smoking behavior and exposure to second-hand smoke. The association between mother's and child's cortisol has been found to be stronger in households with better parenting practices and better parent-child interactions.

The remainder of this section provides more detail on the various data collection activities included in Phase 2 of MIHOPE.

Weekly Logs

The authorizing legislation requires examining how impacts vary across programs. Phase 2 of MIHOPE would address this requirement by exploring how variation in how local home visiting programs were implemented is related to variation in impacts of those programs on parent, child, and family outcomes.

OMB previously approved collection of data on program implementation as part of the Phase 1 data collection package. As part of that package, OMB approved the collection of weekly logs on how home visitors spend their time with families through July 2015 or the child's 15th month, whichever comes first. Phase 2 will extend the collection of logs through June 2016 for all families, or until the family is no longer receiving home visiting services. This is being done to provide more comprehensive information on dosage since each of the evidence-based models provides services past the child's 15th month of age. This information will be especially useful if HHS opts for longer follow-up of outcomes for families in the evaluation. A request for an information collection extension will be submitted in the event that the OMB clearance for data collection expires before June 2016.

In addition, the weekly logs approved in the Phase 1 data collection package have been modified to collect information on visits made by individuals from the home visiting program other than the primary home visitor, such as backup staff that conduct home visits when the primary home visitor is unavailable or specialty staff that conduct visits to address a specific issue. Information being collected from logs is provided in Attachment 3.

Family Follow-up Survey

The family follow-up survey (Attachment 1) will include information on several domains specified in the ACA: infant and child health; child development; parental health and well-being; parenting practices, attitudes, and beliefs; domestic violence; history with the criminal justice system; family economic self-sufficiency; and use of social services. Survey questions will focus on outcomes for which previous studies of home visiting have found effects and on outcomes that would not be available from other sources (such as administrative records).

Table A.1 lists the constructs that will be collected in these various domains, the sources and proposed measures, and whether they will be collected during Phase 1 or 2. In general, measures were chosen because prior research or theory indicates that home visiting programs

may have effects on these outcomes. For example, prior research has found that home visiting programs have favorable impacts on outcomes such as maternal depression, breastfeeding behavior, and access to health care. The follow-up survey will collect information that is not available from other sources, such as administrative data. Some of this information is also collected at baseline, and reassessed at follow-up (such as depressive symptoms).

Direct Parent-Child Interactions

Follow-up data collection will include direct assessments of children's and parents' interactions with each other, specifically using the three bags task and a "clean-up" task. A protocol for these activities is provided in Section H of Attachment 2. These tasks capture a range of parenting outcomes that are direct targets of home visiting programs, including parental sensitivity, cognitive stimulation, positive regard, intrusiveness, negative regard, detachment, relationship quality (degree of relatedness and mutual engagement), and boundary dissolution (parent's inability to maintain an appropriate role in his or her interaction with child). These outcomes require independent assessments (as opposed to self-reports, which may be more likely to be influenced by home visiting programs through raising parents' awareness of preferred or desired responses regarding various types of parenting behaviors). In the proposed task, participants will be given three bags of objects. The first bag will include a board book (such as Goodnight Gorilla), the second bag will include a set of building blocks (such as Lego Duplo), and the third bag will include 2 Little People and 3 farm animals.. All materials will be gender neutral, will not involve sounds or batteries, and the content of each bag are intended to be equally attractive. The book will have few words, so the same book will be provided to both English and Spanish speaking children and parents. Parents are given instructions that are intentionally vague so as to allow parents to display naturally occurring parenting behaviors for about 10 minutes. Coders will subsequently rate the mother on parenting scales and the child will be rated on engagement of the parent, sustained attention, and negativity toward the parent. Children will not be coded for reading behaviors. The task and various adaptions of the task have been successfully administered and coded in a variety of large-scale experimental and longitudinal studies, including the National Evaluation of Early Head Start (Brady-Smith et al., 2000), the ECLS-B (Early Childhood Longitudinal Study—Birth Cohort), and Baby FACES.

When the three bags task has been completed, parents and children will be asked to pick up the objects. Parents will be told to behave as they would at home if they were trying to get their child to do something. The task will be videorecorded and coded for parents' guidance and control strategies, as well as the child's compliance. The task is expected to last about three minutes or when all of the objects are put back in the bags from the three bags task.

Direct Child Assessment

Maternal stimulation of children's language development is a core component of many home visiting programs. Language development in the second year of life is a predictor of longer-term school readiness and achievement. Furthermore, there is evidence of positive effects of home visiting programs in this area. For these reasons, assessment of children's language – particularly their receptive language - is an important outcome variable. A direct assessment of the child's language development will be conducted during Phase 2 using the Preschool

Language Scales-5 Auditory Comprehension Scale (PLS-5), which is an individually administered test that assesses the child's ability to understand language. The child will sit on the mother's lap while the field interviewer administers this test. For Spanish respondents, field staff will use the Spanish version of the PLS-5. At 15 months, toddlers' spoken language capabilities are only just beginning to develop. For this reason, the Auditory Comprehension subtest of the PLS-5 will be used. The Auditory Comprehension cluster measures a child's ability to be attentive and respond to stimuli in the environment and to comprehend basic vocabulary or gestures. A protocol for completing this assessment is provided in Section E of Attachment 2, although the specific questions are not provided because they are proprietary.

Height and Weight

Field staff will have the bottom piece of a stadiometer and a weighing scale when they conduct field visits, which they will use to obtain both the mother's weight and the child's height and weight. Only the bottom piece of the stadiometer will be used because it is sufficient for measuring the child's height, and it can be unwieldy to have the top piece of the stadiometer in a crowded house. Direct measurements of the child's weight and height will provide information on whether the child's growth is within a normal range or exhibits early signs of unhealthy growth trajectories (i.e., risk of obesity or under-development). Measurement of the mother's weight along with self-reported height will provide information on whether the mother is obese, which is associated with a host of other health problems. When measuring weight, if the child is willing, the field interviewer will ask him or her to stand on the weighing scale by him or herself. If the child is unwilling to do so, then the staff person will obtain the mother's weight and then ask her to pick up the child and stand on the scale with the child. The mother's weight will then be subtracted from this total weight to obtain the child's weight. These measures are being collected out of concern that the mother may not accurately report her own weight and may not know her child's current weight and height. A protocol for measuring height and weight is provided in Section F of Attachment 2.

Home Observation for Measuring the Environment Assessment

The Home Observation for Measuring the Environment (HOME) will be collected to assesses the quality and amount of stimulation that the child receives in the home as well as observations of the home environment. These assessments provide information on parenting behavior, including social-emotional responsivity, cognitive stimulation, and harsh parenting. Information needed to score the HOME will be obtained from two sources: (1) parent-reported items that are included in the family follow-up survey, and (2) observations by the Mathematica field staff person when they are in the family's home at follow-up. . Since it does not represent a burden to families, OMB is not being asked to approve the observational component of the HOME assessment. Specifically, it (1) does not require the family to provide any information, and (2) will be conducted at the same time as other in-home aspects of data collection. This is consistent with 44 USC, 5 CFR Ch. 11 (1-1-99 Edition), 1320.3, which indicates that "information" does not generally include facts or opinions obtained through direct observation by an employee or agent of the sponsoring agency or through nonstandardized oral communication in connection with such direct observations. Section K of Attachment 2 shows the areas covered by the observational component of the HOME, although the specific questions are not provided because they are proprietary.

Saliva Collection

If saliva is collected, it will be collected from mothers and children for two purposes: (1) to assess their exposure to smoke by measuring levels of cotinine, a metabolite of nicotine; and (2) to measure levels of cortisol, which will provide a physiological measure of attunement between the mother and child. The protocol for saliva collection is provided in Section C of Attachment 2.

Saliva would be used to measure cotinine because evidence suggests that there is a considerable amount of misreporting of smoking behavior in self-reported surveys. For example, a recent analysis by the Centers for Disease Control (CDC) found that nearly one-fourth of pregnant women who smoked reported they did not smoke, as did 10 percent of other female smokers (Dietz et al., 2011). Perhaps more important, studies of interventions to reduce smoking have found that those who receive services are more likely to misreport whether they smoke at follow-up, which would result in biased estimates of the effects of home visiting programs on smoking (Patrick et al., 1994; Russell, Crawford, & Woodby, 2004; Studts et al., 2006). Using saliva to measure cotinine levels would thus provide unbiased estimates of the effects of home visiting on smoking and exposure to smoke, which is a key predictor of maternal health and child health and development.

Saliva samples would also be used to measure salivary cortisol levels in mothers and children. Cortisol is a biomarker of stress in the body and is frequently used as a measure of stress exposure or chronic stress activation. Previous evaluations have demonstrated that home visiting programs can successfully improve the capacity for cortisol regulation among children in foster care (Mary Dozier, Peloso, Lewis, Laurenceau, & Levine, 2008; M. Dozier et al., 2006) and among medically at-risk infants (Bugental, 2010).

The standard analysis of cortisol is based on the observation that normal cortisol levels follow a circadian rhythm rising rapidly at wake-time and falling over the course of the day, but that "flatter" cortisol functions and higher overall levels of cortisol over the course of the day are associated with growing up in "toxic stress" conditions, including poverty, abuse, and neglect. This type of analysis requires collecting multiple samples of cortisol across the day, which can be time consuming and expensive and can impose a substantial burden on parents.

Because of the cost of the standard strategy, MIHOPE will be using an alternative approach that is based on recent work by Douglas Granger and others. According to this research, the attunement or correlation between a parent's cortisol level and the child's cortisol level is close to zero for very disadvantaged families but higher for better off families, for example, around 0.3 for intact middle class families (Booth, Goslin, Johnson, & Granger, under review; Ruttle, Serbin, Stack, Schwartzman, & Shirtcliff, 2011) Thus, the main hypothesis to be tested in MIHOPE is that the correlation between the mother's and child's levels is higher in the home visiting group than in the control group.

If collected, saliva samples would be collected two times from mothers and children during the data collection follow-up visit: once immediately before the three bags task and once about 20 minutes after the three bags task. Two samples would be collected because cortisol measurement can be fairly imprecise with just one sample.

Although the proposed approach has not been used in large-scale studies, MIHOPE could provide evidence that cortisol can be measured more simply than in the past, greatly reducing the burden to families in future studies.

Table A.1.
Follow-up Data Collection: Domains and Constructs

Domain	Constructs	Source	Proposed measure(s)	In Baseline (Phase 1)	In Follow-up (Phase 2)
Child health and development					
Newborn Health	Overall health; birth weight; length of hospital stay at Birth	PR	Pregnancy Risk Assessment and Monitoring System (PRAMS)	X	X
Infant and Child Health	Overall health; height/weight; special health care needs; injuries; developmental milestones; chronic illnesses; stress; exposure to smoke	DA, PR	U.S. Department of Education; National Center for Education Statistics; items from Early Childhood Longitudinal Study, Birth Cohort (ECLS-B); items from Healthy Families Alaska (HFA) Interview (Duggan et al., 1999); PRAMS; saliva sample (if saliva is collected)		X
Child Development	Language development; social and emotional Development	DA, PR	Preschool Languages Scale-5 Auditory Comprehension Scale, Brief Infant Toddler Social and Emotional Assessment (BITSEA)		X
Parenting					
Parenting Behavior	Breastfeeding	PR	PRAMS	X	X
	Nutrition; sleep routines; cognitive stimulation; parental sensitivity; positive regard; intrusiveness; negative regard; detachment	PR, OA	Baby FACES Parent Interview; Brief Infant Sleep Questionnaire, Three bags Task; HOME (Caldwell & Bradley, 1984; Linver et al., 2002)		X
Child Maltreatment	Harsh parenting and discipline	PR	Items from the Conflict Tactics Scale-Parent Child Version (CTS-PC)		X
	Contact with Cihild Protective Services	PR	Item from Fragile Families Survey		X
Safety, Stress, Paternal Support	Home Safety Environment	PR, OA	PRAMS, HOME	X	X
	Parenting Stress	PR	Parent Stress Index- Short Form (PSI-SF)	X	X
	Father Involvement	PR	Baby FACES Parent Interview	X	X
Parent health and well-being					
Maternal Health	Mother's global health; physical health/illness; depression; anxiety; other mental illness; stress	OA, PR, DA	SF-12 Health Survey Scoring Demonstration; California Health Interview Survey (CHIS); PRAMS; Center for Epidemiologic Studies Depression Scale (CES-D); Generalized Anxiety Scale (GAD-7); Pearlin Mastery Scale saliva sample (if saliva is collected)	X	X

Domain	Constructs	Source	Proposed measure(s)	In Baseline (Phase 1)	In Follow-up (Phase 2)
Maternal Substance Use	Tobacco use	DA	Saliva sample (if saliva is collected)		X
	Tobacco use, substance use; problem alcohol use	PR	PRAMS	X	X
Maternal Reproductive Health	Birth control; desired timing of subsequent births	PR	Items from HFA Survey	X	X
Intimate Partner Violence	Emotional, physical and sexual victimization and perpetration	PR	CTS scales from Supporting Healthy Marriage (SHM) Survey, Women's Experience and Battery Scale (WEB)	X	X
Crime	Maternal criminal involvement: arrests	PR	Items from Youth Build Survey	X	X
Family Self-Sufficiency	Income: Maternal earned income and household income in last month	PR	Supporting Healthy Marriages (SHM) 12-Month Survey	X	X
	Employment: Maternal employment	PR	KS-MO Hard to Employ Survey; Employment Retention and Advancement (ERA) Survey	X	X
	Public Assistance: Receipt TANF, SNAP, WIC, and UI in last month	PR	SHM 12-Month Survey; HFA interview		
	Food Security	PR	Economic Research Service		X
Actual Services					
Child-Related Screenings, Referral, Coordination, and Service Use	Insurance; access to preventive/primary care; usual source of care; immunizations; receipt of well child care; hospitalizations; injuries requiring health care; emergency department visit; early intervention services; child care; other social services; oral health care; prescription drug use	PR	PRAMS; HFA Interview; National Survey of Children's Health; (NSCH), Baby FACES Parent Interview; CHIS; National Survey of Children with Special Health Care Needs (NSCSHCN)	X	X
Mother-related Screenings, Referral, Coordination, and Service Use	Insurance; health care access; use of services; postpartum care; prescription drug use; reproductive health care; mental/substance use care; hospitalization; Intimate partner violence services	PR	Items from HFA Interview; NHANES; NSCSHCN; National Health Interview Survey (NHIS); PRAMS	X	X

Note: Parent-Reports – PR; Observational Assessment – OA; Direct Assessments – DA

A3. Use of information technology for data collection to reduce respondent burden

This study will use information technology, when possible, to minimize respondent burden and to collect data efficiently.

The family follow-up survey will be conducted using computer-assisted telephone interviewing (CATI). CATI allows for the efficient administration of a survey by using skip logic to quickly move to the next appropriate question depending upon a respondent's previous answer.

The three bags parent-child interaction and clean-up task will be video-recorded on a smart card, which allows for the task to be completed efficiently. The use of electronic recording also ensures that the field staff are more focused on proper administration of the task than other tasks (such as coding).

Logs maintained by home visitors will be collected using web-based applications. These applications will allow for the use of skip patterns to reduce the time needed to complete the various data collection procedures. For example, if a home visitor has not visited a family in a given week, the web-based log would record this information but skip over other questions about the family for that week.

Electronic data collection will also allow the research team to track real-time response rates and to monitor data on a regular basis to ensure data quality. The home visitors will receive weekly reports for their own logs, and the research team will also receive weekly reports. These reports will allow the research team to monitor data collection by detailing who has completed the staff survey, whether each home visitor has completed a weekly log for each of their assigned families, and whether each supervisor has completed a weekly log for each of their team members. Electronic data also aid in maintaining and reviewing data quality. Given the study's real-time access to the web-based data, research staff will be able to regularly review item frequencies and cross-tabulations to guard against inconsistent or incorrect values. In addition, the web-based system is designed such that invalid responses cannot be entered (e.g., a 9,000 minute supervisory session) and will prompt the respondent accordingly.

A4. Efforts to identify duplication and use of similar information

Data being collected for MIHOPE are not available in any other form in a consistent manner across the evaluation's approximately 85 sites.

Although many home visiting programs assess parents and children on the domains being collected as part of the family follow-up, those assessments will differ by local program, and local programs will not collect similar information on control group members. The follow-up family survey and direct assessments of parent-child interactions and child development provide the only opportunity to collect this information in a consistent way for all families in the study.

Likewise, information that is being collected through weekly logs is not expected to be available in any other form. To understand variations in actual services received, the study must collect uniform information across models and program sites. No local program is expected to collect the breadth of information needed by the study team from these logs, and some programs may

not collect any of the information in a systematic way. Even if some local programs are collecting some of the information included in the logs, it would be very costly for MIHOPE to align and analyze data from 85 different management information systems (MIS). Program sites vary to the extent that they use an MIS, track service delivery information in the MIS, and track specific service delivery variables. Finally, the study team's experience in conducting analyses in home visiting studies using service delivery data from program site MIS data indicates that the data are often poor quality. Moreover, in past studies it has taken 1–3 months for local programs to send MIS data, making it impractical to monitor data quality and resolve inconsistencies. Real-time monitoring of data quality will be important for obtaining accurate estimates of service delivery.

Finally, although the follow-up survey asks parents to report on their smoking behavior, the collection of saliva, if it is collected, will provide another source of information on smoking and exposure to smoking, to provide a more accurate indicator of smoking status and exposure. For example, although cotinine provides a more reliable measure of recent smoking, it would not pick up less frequent smoking or smoking that had occurred in the past. Self-reports will be valuable for providing a more complete picture of the mother's smoking history, particularly during pregnancy.

A5. Burden on small business

No small businesses are affected by the data collection in this project.

A6. Consequences to collecting information less frequently

Follow-up family data. Follow-up family data will be collected only once for each family. Follow-up family data includes the family follow-up survey, direct parent-child observations, direct child observations, maternal weight and child height and weight measurements, the HOME assessment, and maternal and child saliva collection (if collected). Eliminating follow-up family data will reduce the ability of the evaluation to answer questions about the effectiveness of home visiting programs across the range of child and parent domains specified in the ACA. It would also not be able to estimate the effects of home visiting for subgroups of families, as required by the authorizing legislation.

Logs maintained by home visitors. The ability of the evaluation to assess what aspects of implementation of home visiting program models lead to stronger impacts would be compromised without continued monitoring of home visitor logs. Continuing weekly logs will allow the evaluation to assess variations and patterns of services provided to families, and to link child and family functioning outcomes with whether or not specific activities or tasks were completed during a home visit. More generally, from a cost perspective, it will be important to understand whether frequency of visits or duration of a program have implications for differential outcomes for families.

A7. Special Data Collection Circumstances

There are no special circumstances requiring deviation from these guidelines.

A8. Form 5 CFR 1320.8 (d) and consultations prior to OMB Submission

The 60-day Federal Register notice soliciting comments for the MIHOPE Phase 2 data collection instruments was posted in the Federal Register, Volume 77 Number 148, page 45618 on August 1, 2012. One comment was received. The commentor was supportive of the study and provided three specific suggestions of wording in the measures, which were incorporated into the current version of the instrument. The commentor questioned if the burden estimate for the mother survey was too low. The survey will be pretested with 9 or fewer people and if found to exceed an hour, will be edited so the burden does not exceed the estimated hour.

A9. Justification for Respondent Payments

Tokens of appreciation are important, especially in a longitudinal study, to gain respondents' cooperation and ensure a high response rate and their participation throughout the study, both at the baseline and at the follow-up interview (James, 2001; Mack, Huggins, Keathley, & Sundukchi, 1998; Martin, Abreu, & Winters, 2001). Gifts of appreciation are most appropriately used in Federal statistical surveys with hard-to-find populations or respondents whose failure to participate would jeopardize the quality of the survey data (e.g., in panel surveys experiencing high attrition), or in studies that impose exceptional burden on respondents, such as those asking highly sensitive questions.

Families participating in the study will receive a $25 gift card to parents for completing the 60-minute follow-up family survey. This amount was also offered for completing the baseline interview, as approved in the Phase 1 information collection request. For the field visit, each child will receive a board book (of a $5 value) and the parent will receive a $20 gift card after completing the in-person data collection pieces. If saliva is collected, the parent will receive $15 for providing saliva for herself and her child. The amount is sufficient to encourage families to continue their participation in the follow-up study but is not overly generous. Offering a lower amount could jeopardize the study and actually cost the government more because it could result in a lower retention of families into the study and more effort expended by the evaluation team to successfully keep families in MIHOPE.

A10. Privacy provided to respondents

The study team is committed to protecting the privacy of participants and maintaining the privacy of the data that are entrusted to us; in addition, the study team is experienced in implementing stringent security procedures. Every MDRC and Mathematica employee, including field staff employed for data collection, is required to sign a pledge to assure participants of nondisclosure of private information. Field staff will also be trained in maintaining respondent privacy and data security.

When participants are recruited into the study, they provide signed, informed consent. The consent form includes information about study goals, time required and duration, and the nature of questions that will be asked. Parents will be assured that their responses will be shared only with researchers, will be reported only in the aggregate as part of statistical analyses, and will not

affect their receipt of services. If an applicant is a minor, they are asked to assent to be in the study and their parent or guardian is asked for consent , unless the state emancipated minor laws make this unnecessary. The consent form has been revised to reflect the nature of follow-up data collection and is attached. Parents will be reminded of these assurances and of the nature of follow-up data collection activities and will be asked to verbally consent again before they provide information at follow-up.

Due to the sensitive nature of this research (for example, questions about substance use, domestic violence, child maltreatment, parental harshness, and depression), the evaluation has obtained a Certificate of Confidentiality from HRSA. The Certificate of Confidentiality helps to assure sites and participating mothers that their information will be kept private to the fullest extent permitted by law.

Documents shipped from the field and the document transmittal form that accompanies them will contain only identification numbers so that data cannot be attributed to any particular individual. Security will be maintained on the complete set (and any deliverable backups) of all master survey files and documentation, including sample information, tracking information, baseline, and follow-up data. Personally identifiable information will be removed from study files, which will contain a linking identification number that can be used to match records from one data file to another, for example, linking the physiological information to the questionnaire responses. If collected, saliva will only be analyzed for cotinine and cortisol. Finally, data will be available only to staff associated with the project through password protection and encryption keys.

A11. Justification for sensitive questions

Questions in some components of the MIHOPE follow-up survey are potentially sensitive for respondents. Parents are asked about personal topics, such as child and parental health, substance abuse, salary and income, intimate partner violence and criminal involvement. To improve understanding of how home visiting programs affect families and children, it will be necessary to ask these types of sensitive questions. For example, maternal substance use is a major risk factor for reduced family well-being and child development. It is thus important to identify mothers with depression because maternal depression can be associated with poor parenting and child outcomes. Measuring these outcomes is important because home visiting programs are intended to reduce these behaviors. As noted in section A4, this information will not be available from other data sources in a consistent manner across the 85 sites and for both program group and control group families.

To ensure that parents are aware of the sensitive nature of the questions, the family follow-up survey will contain instructions that explain questions before they are posed and will remind participants that they may refuse to answer any question. Also, respondents will be informed by research staff prior to the start of the interviews or surveys that their answers will be kept private, that results will only be reported in the aggregate, and that their responses will not affect any services or benefits they or their family members receive. These instructions are shown on page 9 of Attachment 1, which contains the proposed follow-up survey.

Collecting accurate information on smoking behavior among mothers is important because previous studies have found that home visiting can reduce smoking (Harding, Galano, Martin, Huntington, & Schellenbach, 2007; Olds et al., 2002). As discussed in sections A2 and A4, relying only on self-reports would substantially reduce the ability of MIHOPE to estimate impacts of home visiting programs for the subgroup of smokers and on smoking behavior. The evidence suggests that saliva samples are excellent at measuring cotinine. A meta-analysis comparing self-reports to biomarkers found sensitivity – a measure of how often a smoker is correctly identified as such using saliva – of 99 percent (Patrick, et al., 1994). Salivary cotinine has also been used to classify smokers as active, passive, infrequent, or regular (Kendrick et al., 1995). Collecting information on cortisol levels will provide a physiological measure of attunement between mother and child, or the matching of behavior, affective states, and biological rhythms. A growing body of research suggests that dyads with more sensitive mothers and their children display greater levels of both behavioral and physiological attunement (Booth, et al., under review; Papp, Pendry, & Adam, 2009; Ruttle, et al., 2011; Sethre-Hofstad, Stansbury, & Rice, 2002; van Bakel & Riksen-Walraven, 2008), thus parents and children in the home visiting group should have more highly correlated cortisol levels than those in the control group.

A12. Estimate of the hour burden of data collection to respondents

Table A.2 shows the annual burden of the activities described in this supporting statement. The team will try to collect follow-up information from all 5,100 families in the study but is assuming 85 percent of families will provide this information, for a total of 4,335 families at follow-up.

The annual burden estimates for site recruitment and Phase 1 data collection efforts are outlined in the first half of Table A.2, and have already been approved by the OMB. The activities that have already been approved include 459 annual burden hours totaling $13,173 for site recruitment activities, and 5,312 annual burden hours totaling $146,091 for Phase 1 data collection efforts.

The annual burden estimates (hours and costs) for Phase 2 data collection efforts are shown in the last panel of Table A.2. The newly requested burden for approval includes 5,389 annual burden hours, for an additional $50,156 in costs. For collecting logs, an hourly wage of $28.70 was used (see Table A.3). This is the mean wage for full-time employees 25 years old and older with a bachelor's degree or higher according to the Bureau of Labor Statistics' Current Population Survey 2011. For collecting data from families, an hourly wage of $11.48 was assumed for mothers, which is the median wage for full-time workers 25 years old or older with less than a high school diploma. For children, an hourly wage of $0 was assumed.

Note that the burden per response for home visitor logs is 0.20 hours for Phase 1 data collection and 0.09 hours for Phase 2. Phase 1 will collect information from logs through the child's 15th months, while Phase 2 would collect log information after the child's 15th month. The burden per response is lower in Phase 2 because fewer families are expected to be receiving home visiting services after the child's 15th month.

The total estimates of burden for the study (including site recruitment, Phase 1 data collection, and Phase 2 data collection) are 10,701 hours and about $196,247 in costs.

Table A.2
Annual Burden Estimates

	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Annual Burden Hours	Average Hourly Wage	Total Annual Cost
Site Recruitment						
Telephone contact with state administrators	49	1	1.00	49	$28.70	$1,406.30
First round visits with state administrators	18	1	1.50	27	$28.70	$774.90
Second round visits with state administrators	15	1	1.50	23	$28.70	$660.10
Visits and calls with local program directors	120	1	3.00	360	$28.70	$10,332.00
Site Recruitment Total				**459**		**$13,173.30**
Phase 1 Data Collection						
Family screening and consent	1,889	1	0.10	189	$25.00	$4,725.00
Family baseline survey	1,700	1	1.00	1700	$25.00	$42,500.00
State administrator interview						
Baseline	8	1	2.00	16	$28.70	$459.20
12 Month	8	1	2.00	16	$28.70	$459.20
Program manager survey						
Part 1, Baseline	29	1	0.50	15	$28.70	$430.50
Part 2, Baseline	29	1	1.00	29	$28.70	$832.30
Part 3, Baseline	29	1	1.00	29	$28.70	$832.30
12 month	29	1	2.00	58	$28.70	$1,664.60
Supervisor survey						
Baseline	23	1	1.25	29	$30.00	$862.50
12 month	23	1	1.25	29	$30.00	$862.50
Home visitor survey						
Baseline	160	1	1.25	200	$30.00	$6,000.00
12 month	160	1	1.25	200	$30.00	$6,000.00
Combined home visitor-supervisor survey						
Baseline	10	1	1.75	17.5	$30.00	$525.00
12 month	10	1	1.75	17.5	$30.00	$525.00
Community service providers survey	510	1	0.10	51	$28.70	$1,463.70
Other home visiting programs survey	142	1	0.10	14	$28.70	$401.80
Supervisor logs	33	60	0.20	396	$28.70	$11,365.20
Home visitor logs	170	60	0.20	2040	$28.70	$58,548.00
Group interview						
Program manager	29	1	1.50	44	$28.70	$1,262.80
Supervisor	33	1	1.50	50	$28.70	$1,435.00
Home visitor	57	1	1.50	86	$28.70	$2,468.20
Home visitor individual interview	57	1	1.50	86	$28.70	$2,468.20
Phase 1 Data Collection Total				**5,312**		**$146,091.00**

(Continued)

Burden for Phase 2 data collection and overall, without collection of saliva, is detailed in the following table:

Table A.2 (Continued)

	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Annual Burden Hours	Average Hourly Wage	Total Annual Cost
Phase 2 Data Collection (Under Review)						
Home visitor logs	170	50	0.09	765	$28.70	$21,955.50
Family follow-up survey	1445	1	1	1445	$11.48	$16,588.60
Direct parent-child interaction	2890	1	0.6	1734	$5.74	$9,953.16
Direct child assessments	1445	1	0.8	1156	$0.00	$0.00
Measuring height and weight	2890	1	0.1	289	$5.74	$1,658.86
Phase 2 Data Collection Total				5,389		$50,156.12
ESTIMATED TOTAL				**10,701**		**$196,247.12**

A13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There is no additional cost burden to respondents of record keepers.

A14. Estimates of costs to federal government

ACF and HRSA are funding these activities. The estimated cost for activities covered in this submission is $12,797,873, or $4,265,958 per year. This includes designing data collection instruments, collecting follow-up family information, and collecting all data on program implementation.

A15. Changes in burden

This is an increase in burden approved under the Maternal and Infant Home Visiting Program Evaluation Phase 1 data collection package (0970-0402). The increase is the result of ongoing information collection for the mandated evaluation.

A16. Tabulation, analysis, and publication plans and schedule

Site recruitment activities for Phase 1 of MIHOPE began in February 2012 (as approved 1/26/2012 under OMB clearance 0970-0402). States were contacted for the first time between February 2012 and December 2012. Local program sites will be enrolled in the study on a rolling basis from September 2012 through June 2013. Within a site, staff would be surveyed at the time the site enters the study and one year later. In each site, it is expected to take 12-18 months to enroll women, so that sample recruitment and baseline data collection is expected to end in December 2014.

Phase 1 data collection instruments were developed and approved by OMB, including a family baseline survey and all implementation research surveys and logs (OMB clearance 0970-0402,

approved 7/12/2012). Phase 1 will produce a report to Congress in 2015. This report will include information on the characteristics of families participating in the evaluation. The report will also include information on organizational factors that will be collected from the implementing agencies.

Phase 2 will include follow-up data collection on family outcomes and results will be presented in three reports.

- The first report will describe findings on program implementation using the baseline and follow-up web-based surveys of program staff and as much data from weekly logs as is available.
- A second report will describe the estimated effects of the programs on the range of domains specified in the ACA and for key groups of families and programs. If saliva is collected, this report will include information obtained from those saliva samples to describe how home visiting services and impacts differed between smokers and nonsmokers. It will also describe the effects of home visiting, if scaled up, to affect health care disparities and health care systems. The second report will further include results from the MIHOPE economic evaluation, including information on program costs and cost-effectiveness for achieving impacts on key outcomes.
- A third report will describe the relationship between the features of home visiting programs and their effects.

A18. Reasons for not displaying the OMB approval expiration date

All instruments will display the expiration date of OMB approval.

A19. Exceptions to Certification Statement

No exceptions are necessary for this information collection.

REFERENCES

Booth, A., Goslin, M., Johnson, D., & Granger, D. A. (under review). Cortisol concordance within families: Relationship quality, individual adjustment, and contextual strain moderators.

Brady-Smith, C., O'Brien, C., Berlin, L., Ware, A., Fauth, J., & Brooks-Gunn, J. (2000). *Child-parent interaction rating scales for the Three-Bag assessment: 36-month wave*. Teachers College, Columbia University. New York.

Bugental, D. B. S., Alex; Lynch, Colleen. (2010). Effects of an Early Family Intervention on Children's Memory: The Mediating Effects of Cortisol Levels. *Mind, Brain, and Education, 4*(4), 159-170.

Dietz, P. M., Homa, D., England, L. J., Burley, K., Tong, V. T., Dube, S. R., et al. (2011). Estimates of Nondisclosure of Cigarette Smoking Among Pregnant and Nonpregnant Women of Reproductive Age in the United States. *American Journal of Epidemiology, 173*(3), 355-359.

Dozier, M., Peloso, E., Lewis, E., Laurenceau, J.-P., & Levine, S. (2008). Effects of an attachment-based intervention on the cortisol production of infants and toddlers in foster care. *Development and Psychopathology, 20*(3), 845-859. doi: 10.1017/S0954579408000400

Dozier, M., Peloso, E., Lindhiem, O., Gordon, K., Manni, M., & Sepulveda, S. e. a. (2006). Developing evidence-based interventions for foster children: An example of a randomized clinical trial with infants and toddlers. *Journal of Social Issues, 62*, 767-785.

Harding, K., Galano, J., Martin, J., Huntington, L., & Schellenbach, C. J. (2007). Healthy Families America Effectiveness: A Comprehensive Review of Outcomes. *Journal of Prevention & Intervention in the Community, 34*(1/2), 149-179.

James, T. (2001). *Results of the Wave 1 incentive experiment in the 1996 survey of income and program participation.* Paper presented at the Proceedings of the Section of Survey Research Methods, Alexandria, VA.

Kendrick, J. S., Zahniser, S. C., Miller, N., Salas, N., Stine, J., Gargiullo, P. M., et al. (1995). Integrating smoking cessation into routine public prenatal care: the Smoking Cessation in Pregnancy project. *American Journal of Public Health, 85*(2), 217-222.

Mack, S., Huggins, V., Keathley, D., & Sundukchi, M. (1998). *Do monetary incentives improve response rates in the survey of income and program participation?* Paper presented at the Proceedings of the Section on Survey Research Methods, Alexandria, VA.

Martin, E., Abreu, D., & Winters, F. (2001). Money and motive: Effects of incentives on panel attrition in the survey of income and program participation. *Journal of Official Statistics, 17*, 267-284.

Olds, D. L., Robinson, J., O'Brien, R., Luckey, D. W., Pettitt, L. M., Henderson, C. R., et al. (2002). Home Visiting by Paraprofessionals and by Nurses: A Randomized, Controlled Trial. *Pediatrics, 110*(3), 486-496. doi: 10.1542/peds.110.3.486

Papp, L. M., Pendry, P., & Adam, E. K. (2009). Mother-adolescent physiological synchrony in naturalistic settings: Within-family cortisol associations and moderators. *Journal of Family Psychology, 23*(6), 882.

Patrick, D. L., Cheadle, A., Thompson, D. C., Diehr, P., Koepsell, T., & Kinne, S. (1994). The Validity of Self-Reported Smoking: A Review and Meta-Analysis. *American Journal of Public Health, 84*(7), 1086.

Russell, T., Crawford, M., & Woodby, L. (2004). Measurements for Active Cigarette Smoke Exposure in Prevalence and Cessation Studies: Why Simply Asking Pregnant Women Isn't Enough. *Nicotine Tob Research, 5*(Suppl 2), S141-151.

Ruttle, P. L., Serbin, L. A., Stack, D. M., Schwartzman, A. E., & Shirtcliff, E. A. (2011). Adrenocortical attunement in mother-child dyads: Importance of situational and behavioral characteristics. *Biological Psychology, 88*(1), 104-111.

Sethre-Hofstad, L., Stansbury, K., & Rice, M. A. (2002). Attunement of maternal and child adrenocortical response to child challenge. *Psychoneuroendocrinology, 27*, 731-747.

Studts, J. L., Ghate, S. R., Gill, J. L., Studts, C. R., Barnes, C. N., LaJoie, A. S., et al. (2006). Validity of self-reported smoking status among participants in a lung cancer screening trial. *Cancer Epidemiology Biomarkers Prevention, 15*(10), 1825-1828.

van Bakel, H. J. A., & Riksen-Walraven, J. M. (2008). Adrenocortical and Behavioral Attunement in Parents with 1-Year-Old Infants. *Developmental Psychobiology, 50,* 196-201.

Maternal and Infant Home Visiting Program Evaluation (MIHOPE)

OMB Information Collection Request
0970 - 0402

Supporting Statement

Part B

January 2013

Revised June 2013

Part B. COLLECTION OF INFORMATION USING STATISTICAL METHODS

B1. Sampling

The sampling plan for MIHOPE was described in the supporting statement for Phase 1 data collection activities. As described there, MIHOPE will seek to recruit approximately 5,100 families at baseline–divided between program and control groups – from approximately 85 local program sites in 12 states. Families are generally eligible for the study if the mother is pregnant or the family has a child under six months old, the mother is 15 years or older, and the mother is available to complete the baseline family survey. Local sites are being chosen to meet several criteria: (1) operating programs that have existed for at least two years, (2) evidence of enough demand for home visiting services that they could provide a control group, (3) no evidence of severe implementation problems that would interfere with the program's ability to participate in the study, and (4) a contribution to the diversity of sites and families for purposes of estimating effects for important subgroups of families. Families are being recruited into the study by Mathematica's survey research staff, who will visit families to obtain informed consent when home visitors determine whether a family is eligible or soon after that determination has been made.

The OMB supporting statement for Phase 1 data collection also indicated that the sample is adequate to detect policy relevant impacts of home visiting, both overall, for key subgroups, and for each of the four evidence-based models included in the evaluation. For example, for the pooled sample, the study is powered to detect impacts of about .06 standard deviations. In addition, the study is powered to be able to detect differences across subgroups of about .12 standard deviations. Further detail on the universe and sampling plan for MIHOPE, approved in July 2012, can be found in Appendix A.

As of May 8, 2013, 76 percent of families identified as eligible for MIHOPE have consented to be in the study, and 100 percent of families who have provided consent have completed the baseline interview. Materials approved by OMB in Phase 1 assumed that 90 percent of eligible families would consent to be in the study. This does not affect the study's sample size, which is still expected to include 5,100 families who provide consent. One implication of the lower consent rate is that approximately 1,000 additional eligible families will be needed to obtain 5,100 study participants. We do not expect this to affect the burden to individuals, however, since most eligible families who have not provided consent have been unlocatable (for example, they have not answered the phone), so that the consent process has not used any of their time.

B2. Procedures for collection of information

This section describes the collection of follow up data for MIHOPE families when the focal child is 15 months old. Data collection with families at follow up will include conducting a family survey, a video-recorded parent-child interaction (three bags task plus a clean-up task), a child language assessment (PLS-5), and gathering mother and child's height and weight informationand possibly saliva. Follow-up data collection will begin in summer 2013 when the focal children in the first families enrolled in the study are likely to be 15-months old. Best practices will be followed for conducting the Phase 2 data collection, including training and certifying staff on data collection procedures and monitoring data collection to ensure that high quality data are collected and high response rates are achieved. Our follow-up data collection methodology builds on the MIHOPE baseline methodology in several respects:

- The same field interviewer who met with a family at baseline will be assigned to the follow-up visit whenever possible to help maintain rapport with families and maximize response rates
- Computer assisted telephone interviewing (CATI) will be used for the follow-up parent interview to provide consistent monitoring of survey data collection, ensure high quality data are being collected, and provide improved data security (since no data need to be transmitted from laptops in the field).
- CATI allows for the development of a complex instrument with multiple pathways for different families and scenarios (for example, families in which the mother is no longer the child's primary caregiver).
- The family survey will be conducted via telephone to ensure privacy for the parent (because no one else in the home can overhear the conversation).
- Tokens of appreciation will be provided to increase families' willingness to respond to the follow up survey.
- Field staff will be trained and certified using standardized procedures will ensure high quality data collection.

Conducting the Follow-Up Family Survey. To collect follow-up data from MIHOPE participants, the study team will adopt the method that was successfully used on the FACES study. As soon as families become eligible for the 15-month follow up, telephone interviewers at Mathematica's Survey Operations Center (SOC) will contact them via telephone and attempt to complete the follow-up family survey. Families will be reminded that they have already consented to the follow-up visit when they agreed to participate in the MIHOPE study at baseline.

Some families may be difficult to initially reach by telephone. For those families, field staff will go to the families' home and help them initiate a call to the SOC via cellular phone to complete the family survey.

Conducting the Follow-Up In-Home Visit. If the follow-up interview is conducted without the field staff going to the families' home, telephone interviewers will schedule a visit for field staff to the families' home to conduct the in-home portion of data collection: video-recorded parent-child interaction, the child language assessment, the HOME observation and to collect the mother weight and child's height and weight information. This approach— attempting to complete the follow-up surveys by telephone prior to sending field staff to the home—is efficient and cost-effective because it reduces the amount of time interviewers spend in some families' homes.

Field interviewers will greet the family upon arrival. They will re-introduce the study, answer any questions the family has about continued participation in the study, and provide assurances of privacy. Field staff will also inform the family of the voluntary nature of their participation. As part of the follow up visit, field staff will (1) complete the follow-up family survey, if it has not already been completed by the SOC; (2) conduct a video-recorded parent-child interaction (three bags task); (3) conduct a child language assessment (PLS-5); (4) take the motherand the child's height and weight information; and (5) possibly collect saliva from the mother and child.

Field staff will be trained to be flexible when approaching families for the follow up data collection. For example, it may be necessary to schedule more than one visit to complete all data collection pieces or it

may be necessary to exercise flexibility in the order of the data collection pieces depending on the child's alertness levels. For example, field staff may arrive at the home while the infant is sleeping and may start with the family survey and HOME observation measures first. Or if field staff arrive at the home and the infant is awake and alert, they may start with the Three-Bags or the PLS-5. Parents will receive a $25 gift card for completing the survey. For the field visit, each child will receive a small gift (of a $5 value) and the parent will receive a $20 gift card after completing the in-person data collection pieces. This amount is comparable to what is being offered at baseline.

Saliva Collection. If ACF decides to collect saliva, the field staff person will be collecting saliva from the mother and child. The mother will be able to opt out of providing saliva and can refuse to allow saliva to be collected from the child.

The field staff person will collect a saliva sample. Procedures for collecting saliva are based on discussions with Douglas Granger, Professor of Nursing, Public Health, and Medicine and Director of the Center for Interdisciplinary Bioscience Research at Johns Hopkins University (JHU) and will follow procedures he is designing to be implemented in the National Children's Study.

Saliva will be collected from the mother by asking her to move her jaw as if she was chewing her favorite food in order to stimulate the production of saliva. She will then be asked to gently force saliva through a collection device into a 2 mL storage vial until 1 ml has been collected. Collecting saliva from children under the age of six involves placing a foam rod-shaped swab under the children's the tongue for 60-90 seconds. The saliva saturated swabs are placed in a storage vial.   All samples will be immediately placed on ice.

To protect the family's privacy, the vials will be labeled with a barcode. A second copy of the barcode will be attached by the field staff person to a paper form that contains the individual's study id and other identifiers such as the woman's name and contact information.

After leaving the house, the field staff person will ship the vials overnight to Mathematica's SOC, where it will be logged in and kept in a locked laboratory freezer until it is ready for shipment. Samples will be shipped to the laboratory (e.g., at JHU) for analysis on a periodic basis. For example, samples might be shipped once 1,000 have been obtained or once every quarter.

A laboratory has not yet been chosen, but our current plan, depending on costs, is to use the JHU Center for Interdisciplinary Salivary Bioscience Research. That lab analyzes 60,000-90,000 saliva samples each year. If JHU is used, once the samples arrive at the lab in Baltimore, they will be stored in freezers that are located in a secure facility that is FISMA compliant.

All data files, including physiological data, will be marked with a research id. No identifiers will be maintained in these files. Names, contact information, case identification, and Social Security numbers will be excluded from these data files. Study data files will contain a linking identification number that can be used to match records from one data file to another, for example, linking the physiological information to the questionnaire responses.

Logs Maintained by Home Visitors. Data about service delivery will be collected through weekly web-based logs. For sites in which home visitors do not have regular access to the internet, paper

versions of the logs will be offered. Home visitors can complete the paper forms and a support person in the site can enter these data using the site's computers.

B3. Maximizing response rates

Minimizing sample attrition is of utmost importance to any longitudinal study. It is likely that many MIHOPE families will be highly mobile, and therefore there will be the risk of attrition at follow up. The target for the 15 month follow-up data collection for MIHOPE is an overall response rate of 85 percent, but the actual response rate achieved will likely be somewhere between 80 and 85 percent. Several strategies will be adopted to mitigate the risk of attrition at follow up:

- Under Phase 1 of MIHOPE, mail locating cards and welcome baby letters to families in the sample. These are initial attempts to obtain updated address and telephone information and maintain contact with families in preparation for follow up. These documents were reviewed and approved with the Phase 1 information collection request.
- Use the contact lists generated from the baseline data collection and employ Mathematica's highly effective locating techniques.
- Train field staff in how to gain cooperation and avoid refusals.
- Provide tokens of appreciation at both baseline and follow up to encourage participation.

Tracking Participants. Mathematica's Sample Management System (SMS) will be used to track sample recruitment, survey response rates and potential sample attrition. Tracking begins with the initial entry of a family into the SMS. Baseline data collection protocol gathers detailed information from families in order to find them at the time of the follow up interview; collecting names, dates of birth, Social Security numbers (if possible), addresses and phone numbers (home and work) for the family and for up to three relatives or friends who will know how to reach the family. As indicated in the informed consent form that participants sign, Social Security numbers are used both for tracking purposes and to link to state, county, and federal administrative data sources.

Between the baseline and follow up surveys, attempts will be made to reach each family by mail up to three times to request updated contact information for tracking purposes. As an added motivator, and as approved by OMB as part of the Phase 1 data collection package, families will receive $5 if they return a mailing with any updated contact information. The SMS will generate reports that list families who are due for their tracking letter and print the letter and address label for mailing. Letters that are returned as undeliverable will be sent to our tracing department for locating and will be re-mailed to the updated address. The SMS will generate reports that list families who are due for their 15-month follow up visit. Families that appear on the list will begin the locating process to verify their telephone and address information. These efforts will include a letter mailed to families reminding them that it is time for their follow up interview and to please call Mathematica's toll-free number to complete the family survey as soon as possible (Attachment 4). Any letters that come back from the post office as undelivered will be sent to our tracing department for locating and then remailed to the updated address. Families who receive the letter but do not call in for the family survey will be contacted by telephone. The tracing department will attempt to contact the relatives and friends given at baseline for any families who we cannot reach by telephone in order to obtain the family's current address and phone number.

Locating Participants. Although the outlined strategies to track participants between baseline and follow-up will likely result in lower attrition rates, additional techniques will be employed to ensure a high response rate is achieved at follow up from this mobile population. Mathematica has extensive experience conducting studies with mobile and hard-to-reach populations and has developed several techniques to locate these populations. Locating can be costly, depending on which methods are used. In general, mailing letters and receiving updated information via returned mail is less expensive than electronic database searches; electronic database searches are less expensive than locators calling neighbors or other contacts; and telephone tracing is less expensive than in-person field locating. The least expensive methods (mailing and electronic tracing) will be used before moving to more expensive methods (telephone tracing and in-person locating). As preparations to conduct the follow-up data collection get underway, the following process for locating participants will be employed: (1) pre-field mailing and electronic locating, (2) in-house electronic database searches and telephone tracing, and as needed, (3) field locating.

1. *Pre-Field Locating.* Letters (Attachment 4) will be mailed to all families who are due for their 15-month follow-up visit, to invite them to call Mathematica via a toll-free number to complete the follow-up family survey and schedule a visit for the in-person data collection. Any letters that are returned with updated information will be re-mailed to the new address.

   National locating databases, such as Accurint and the National Change of Address Service (NCOA) are cost-effective methods for obtaining up-to-date contact information for sample members, and procedures have been developed that ensure the privacy of the data used to locate individuals. Each month, a locating file will be sent containing contact information from the baseline data or most recent update (including last known address, and date of birth) to Accurint or NCOA. These vendors will process the file through three steps. First, all addresses will be updated to the most recent address on record at the U.S. Post Office. Second, the file will be processed using ZIP+4, which cleans the address to match U.S. Postal Service formats and appends the four-digit ZIP extension. Third, the file will be matched with a telephone number database that adds the most recent telephone number to the file.

2. *In-House Locating.* Custom database searches and telephone contacts given at baseline by the family will be used when pre-field locating does not yield a valid telephone number or address for families. Mathematica's specialized locating staff uses searchable databases, directory assistance services, reverse directories, and contacts with neighbors and community organizations to obtain current contact information.

3. *Field locating.* The remaining un-locatable families will be assigned to field staff that will employ proven techniques for finding hard-to-find populations. They may approach neighbors residing in close proximity to the families' last known address or the contact persons given at baseline, and rely on neighborhood resources such as local post offices, churches, bars, homeless shelters, or community centers as sources of information. In particular, those doing in-person locating will be trained not to reveal any private information about the participant to any informants, including the study's name or unique details about

the study. All field staff will be equipped with cellular telephones so that families, once found, can conduct the follow up interview and complete the in-home activities on the spot.

Logs maintained by home visitors. Strategies for maximizing response rates are similar to those described above for the surveys of families at participating home visiting program sites. When the site enters the study, the research team will explain to program staff the importance of the logs for advancing the field of home visiting in general and the MIECHV program in particular. Research staff will closely monitor weekly log completion reports. They will send program staff two weekly messages (Attachment 5). The first message will remind staff to complete their logs. The second message will document the data that were entered in the previous log by that staff person, thank the staff member for the data provided, and remind those who have not yet completed the previous week's log to do so.

Non-response bias analysis. Although all efforts will be made to obtain information on a high proportion of families, a non-response analysis will be conducted to determine whether the results may be biased by non-response. In particular, two types of bias will be assessed: (1) whether estimated effects among survey respondents apply to the full study sample, and (2) whether program group respondents are similar to control group respondents. The former type of bias affects whether results from the study can be generalized to the wider group of families involved in the study, while the second assesses whether the impacts of the programs are being confounded with pre-existing differences between program group and control group respondents.

To assess non-response bias, several tests will be conducted.

- The proportion of program group and control group respondents will be compared to make sure the response rate is not significantly higher for one research group.
- A logistic regression will be conducted among respondents. The "left hand side" variable will be their assignment (program group or control group) while the explanatory variables will include a range of baseline characteristics. An omnibus test such as a log-likelihood test will be used to test the hypothesis that the set of baseline characteristics are not significantly related to whether a respondent is in the program group. Not rejecting this null hypothesis will provide evidence that program group and control group respondents are similar.
- Impacts from administrative records sources – which are available for the full sample – will be compared for the full sample and for respondents to determine whether there are substantial differences between the two.
- Baseline characteristics of respondents will be compared to baseline characteristics of non-respondents. This will be done using a logistic regression where the outcome variable is whether someone is a respondent and the explanatory variables are baseline characteristics. An omnibus test such as a log-likelihood test will be used to test the hypothesis that the set of baseline characteristics are not significantly related to whether a respondent is in the program group. Not rejecting this null hypothesis will provide evidence that non-respondents and respondents are similar.

If any of these tests indicate that non-response is providing biased impact estimates, a standard techniq ue such as multiple imputation or weighting by the inverse probability of response will be used to determine the sensitivity of impact estimates to non-response.

B4. Pre-testing

As part of Phase 2, the study team will use pretesting to identify revisions to be made to materials, procedures, and instruments for follow-up data collection. We will reach out to home visiting programs in either the Washington, DC or New Jersey areas to identify 9 or fewer families (including both English and Spanish-speaking participants) with a child aged 15 months and recruit them to pretest the CATI follow-up survey and all in-home instruments and procedures. The study team will attempt to recruit participants that represent the diversity of the MIHOPE sample (including linguistic, ethnic, racial, and geographic diversity).

When pretesting the follow-up survey, the interviewer will begin by introducing the study, assuring privacy and reiterating that participation in the survey is voluntary. The interviewer will also ask for permission to audio-record the interview. The interviewer will ask the questions exactly as worded and will follow up with specific probes if any questions seem confusing. The pretest will include cognitive testing and debriefing with the parent and interviewer after the interview is completed. Cognitive interviews will investigate parents' understanding of questions, and ease or difficulty of responding. As part of cognitive interviewing, an interviewer will administer the questions while a second team member listens to the interview and codes for parent hesitation and any indication of lack of understanding. After the interview, we will discuss with parents any questions or confusion they may have had. Debriefings with project staff and interviewers will investigate the ease of administration of the survey instrument. The telephone interviews and subsequent cognitive interviewing with respondents will be recorded so that survey management staff can hear the recordings and obtain accurate estimates of the length of the interview for OMB burden estimates.

Pretesting will also be conducted for the procedures and data collection instruments collected in the home. The purpose of the pretest will be to test the in-home protocols under realistic conditions. During the visit, staff will first introduce the study and inform families that participation in the pretest is voluntary and that the data collected will be kept private. Staff will then conduct the various in-home instruments taking into account the baby's alertness or sleep state to dictate the order of items to be done. Each visit will end with a short debriefing to solicit feedback about the parent's experience. The debriefings will assess the ease of administering the instruments, the handling of the equipment (video camera, weighing scale and cell phone), and identify any trouble spots and solutions for overcoming them.

Results of the pretests will be sent to OMB, and any resulting modifications to instruments will be submitted as nonsubstantive changes for OMB approval.

B5. Consultants on statistical aspects of the design

There are no consultants on the statistical aspects of Phase 2. We have drawn on the expertise of MIHOPE team members including Charles Michalopoulos and Howard Bloom of MDRC.

REFERENCES

Booth, A., Goslin, M., Johnson, D., & Granger, D. A. (under review). Cortisol concordance within families: Relationship quality, individual adjustment, and contextual strain moderators.

Brady-Smith, C., O'Brien, C., Berlin, L., Ware, A., Fauth, J., & Brooks-Gunn, J. (2000). *Child-parent interaction rating scales for the Three-Bag assessment: 36-month wave*. Teachers College, Columbia University. New York.

Bugental, D. B. S., Alex; Lynch, Colleen. (2010). Effects of an Early Family Intervention on Children's Memory: The Mediating Effects of Cortisol Levels. *Mind, Brain, and Education, 4*(4), 159-170.

Dietz, P. M., Homa, D., England, L. J., Burley, K., Tong, V. T., Dube, S. R., et al. (2011). Estimates of Nondisclosure of Cigarette Smoking Among Pregnant and Nonpregnant Women of Reproductive Age in the United States. *American Journal of Epidemiology, 173*(3), 355-359.

Dozier, M., Peloso, E., Lewis, E., Laurenceau, J.-P., & Levine, S. (2008). Effects of an attachment-based intervention on the cortisol production of infants and toddlers in foster care. *Development and Psychopathology, 20*(3), 845-859. doi: 10.1017/S0954579408000400

Dozier, M., Peloso, E., Lindhiem, O., Gordon, K., Manni, M., & Sepulveda, S. e. a. (2006). Developing evidence-based interventions for foster children: An example of a randomized clinical trial with infants and toddlers. *Journal of Social Issues, 62*, 767-785.

Harding, K., Galano, J., Martin, J., Huntington, L., & Schellenbach, C. J. (2007). Healthy Families America Effectiveness: A Comprehensive Review of Outcomes. *Journal of Prevention & Intervention in the Community, 34*(1/2), 149-179.

James, T. (2001). *Results of the Wave 1 incentive experiment in the 1996 survey of income and program participation.* Paper presented at the Proceedings of the Section of Survey Research Methods, Alexandria, VA.

Kendrick, J. S., Zahniser, S. C., Miller, N., Salas, N., Stine, J., Gargiullo, P. M., et al. (1995). Integrating smoking cessation into routine public prenatal care: the Smoking Cessation in Pregnancy project. *American Journal of Public Health, 85*(2), 217-222.

Mack, S., Huggins, V., Keathley, D., & Sundukchi, M. (1998). *Do monetary incentives improve response rates in the survey of income and program participation?* Paper presented at the Proceedings of the Section on Survey Research Methods, Alexandria, VA.

Martin, E., Abreu, D., & Winters, F. (2001). Money and motive: Effects of incentives on panel attrition in the survey of income and program participation. *Journal of Official Statistics, 17*, 267-284.

Olds, D. L., Robinson, J., O'Brien, R., Luckey, D. W., Pettitt, L. M., Henderson, C. R., et al. (2002). Home Visiting by Paraprofessionals and by Nurses: A Randomized, Controlled Trial. *Pediatrics, 110*(3), 486-496. doi: 10.1542/peds.110.3.486

Papp, L. M., Pendry, P., & Adam, E. K. (2009). Mother-adolescent physiological synchrony in naturalistic settings: Within-family cortisol associations and moderators. *Journal of Family Psychology, 23*(6), 882.

Patrick, D. L., Cheadle, A., Thompson, D. C., Diehr, P., Koepsell, T., & Kinne, S. (1994). The Validity of Self-Reported Smoking: A Review and Meta-Analysis. *American Journal of Public Health, 84*(7), 1086.

Russell, T., Crawford, M., & Woodby, L. (2004). Measurements for Active Cigarette Smoke Exposure in Prevalence and Cessation Studies: Why Simply Asking Pregnant Women Isn't Enough. *Nicotine Tob Research, 5*(Suppl 2), S141-151.

Ruttle, P. L., Serbin, L. A., Stack, D. M., Schwartzman, A. E., & Shirtcliff, E. A. (2011). Adrenocortical attunement in mother-child dyads: Importance of situational and behavioral characteristics. *Biological Psychology, 88*(1), 104-111.

Sethre-Hofstad, L., Stansbury, K., & Rice, M. A. (2002). Attunement of maternal and child adrenocortical response to child challenge. *Psychoneuroendocrinology, 27*, 731-747.

Studts, J. L., Ghate, S. R., Gill, J. L., Studts, C. R., Barnes, C. N., LaJoie, A. S., et al. (2006). Validity of self-reported smoking status among participants in a lung cancer screening trial. *Cancer Epidemiology Biomarkers Prevention, 15*(10), 1825-1828.

van Bakel, H. J. A., & Riksen-Walraven, J. M. (2008). Adrenocortical and Behavioral Attunement in Parents with 1-Year-Old Infants. *Developmental Psychobiology, 50*, 196-201.