

Qualitative Assessment of Mothers' Attitudes Toward Collecting Biological Specimens to Study Risk Factors for Birth Defects and Preterm Delivery in the National Birth Defects Prevention Study

**Proposed new data collection to supplement
OMB 0920-0010**

National Birth Defects Prevention Study

November 20, 2006

[Revised March 15, 2007](#)

[\[Based on HHS review comments\]](#)

Project Officer:

Margaret Honein, PhD, MPH
BDDD/NCBDDD/CDC
MS E-86
1600 Clifton Road NE
Atlanta, Georgia 30333

Tel: (404) 498-3921
Fax: (404) 498-3040
email: mrh7@cdc.gov

Qualitative Assessment of Mothers' Attitudes Toward Collecting Biological Specimens to Study Risk Factors for Birth Defects and Preterm Delivery in the National Birth Defects Prevention Study

**Proposed New Data Collection to Supplement
The National Birth Defects Prevention Study, OMB 0920-0010**

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

General Scientific Issues

The genetic contribution to disease and health outcomes is becoming more evident. As a result, one of CDC's top priorities is to incorporate genetics into public health research and practice. A critical component for genetic and gene-environment studies is the collection of biological specimens. For population based gene/environment studies, collection must be convenient for the participant and provide high-quality DNA and DNA quantity sufficient for current molecular technology. Participation and non-participation in the collection of biological specimens is not fully understood. From the literature and our own experience, participation in studies involving the collection of genetic material is low, particularly among minority populations (Cozier et al 2004, Le Marchand et al 2001, Crider et al 2006). Gathering information on biologics

participation is important to the success of studies that involve genetics.

Low participation rates in the collection of biological specimens severely hamper genetic studies. ~~To capture the genetic variation within the larger population, genetic material from all racial and ethnic groups must be proportionately represented.~~ Identifying the concerns that are relevant to specific racial and ethnic groups, developing strategies that respond to these concerns, and identifying acceptable methods of cell collection to increase DNA yield will make genetic studies more powerful.

A number of studies, including focus group discussions, have been conducted to analyze the attitudes of minority populations toward medical and genetic research (Singer et al 2004, Shavers et al 2002, Furr 2002, Schulz et al 2003, Wong et al 2004). These studies indicate there are diverse ethnic concerns about participation in medical and genetic research, including concerns by all minority populations regarding potential discrimination based on population-specific genetic risk factors for disease and a lower level of trust of all medical research among the African American population. Decreased participation of African Americans in medical research may adversely affect efforts to address disparities in health status and limit the ability of research findings to benefit them.

Specific Aims

We will conduct multiple focus groups to:

- 1) Assess the attitudes of mothers who participated and mothers who did not participate in the collection of cheek cell specimens (including predominantly

African American respondents) for the National Birth Defects Prevention Study (NBDPS).

- 2) Gain an understanding of the barriers that non-participants face to help the NBDPS more effectively implement strategies to increase response rates among this group.
- 3) Determine whether there are alternative forms of specimen collection that would be more acceptable to respondents as well as increase quality and quantity of DNA.

CDC scientists from the Coordinating Center for Health Promotion—including the National Birth Defects Prevention Study (NBDPS) in the National Center on Birth Defects and Developmental Disabilities (NCBDDD), the Pregnancy Risk Assessment Monitoring System (PRAMS) in the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), and the Office of Genomics and Disease Prevention (OGDP)—are collaborating on this project. Among the three collaborating Centers within the Coordinating Center for Health Promotion, NCBDDD's National Birth Defects Prevention Study (NBDPS) provides a unique opportunity for exploring the barriers and motivations toward collection of genetic material. As a result, the proposed focus groups are an expansion of data collection within the NBDPS, which was approved by OMB (#0920-0010) and expires on 5/31/2009. The proposed focus group project will recruit mothers who participated in the maternal interview for the NBDPS with the goal of gaining insight into the barriers and motivations women have for participating in the collection of biological specimens.

NBDPS Background

The NBDPS is a nine-site, case-control study that consists of three components:

- 1) The first is surveillance used to identify and collect information on infants with major birth defects.
- 2) The second is a telephone interview of case and control mothers to collect information about their pregnancy and medical history to determine environmental risk factors.
- 3) Third, the NBDPS is currently collecting cheek cells from the case and control infants and their parents in order to identify genetic risk factors. In order to determine significant differences in environmental and genetic risk factors between cases and controls, a large number of infants from a variety of demographic groups are required.

Currently, more than 24,000 mothers have been interviewed as part of the NBDPS.

Approximately 70% of eligible mothers agree to participate in the maternal interview. However, in Atlanta, less than 50% of those interviewed return a biologic sample. The lowest biologics participation, in Atlanta, is among African-American (34.9%), Spanish-speaking Hispanic (32.2%), and less- educated Caucasian mothers (48.0%) (Crider et al 2006). Biologics participation rates vary for each NBDPS site. The range of biologics participation for mothers at NBDPS sites is 27 to 68%, with the exception of two sites, which have biologics participation rates above 75%. Two of the collaborating study sites have conducted focus groups on biologics participation. However, the methodology yielded such low participation rates (some discussion groups had 0 to 1 participants) that the information generated had limited utility (unpublished results). Atlanta includes demographic groups with the lowest biologics participation. Thus, conducting the focus group discussions that address barriers to participation in collection of genetic material in Atlanta may provide valuable data needed to improve the response rate in Atlanta and the NBDPS among those groups with low participation rates. We acknowledge that

the proposed data collection will ~~not be have limited~~ generalizability to other sites, but may still provide useful, although limited, insight into recruitment issues.

In addition to the low biologic participation rates, DNA yields from self-collected cheek cells are less than optimal. The collection of blood would increase DNA yields but may further diminish biologic participation. In the NBDPS, following completion of a computer-assisted telephone interview (CATI), mothers are sent a cheek cell sample kit to administer to themselves, their child, and the child's father. The cheek cell sample kit includes cytobrushes. The proposed focus groups will assess why mothers did or did not participate in the collection of cheek cells, and will also allow us to determine if there is an alternative form of cell collection that would provide more DNA while maintaining participation rates.

Authority for proposed data collection:

The Centers for Disease Control and Prevention (CDC), an Agency of the Department of Health and Human Services, is authorized to collect this information under provisions of Sections 317C and 301 of the Public Health Services Act (42 U.S.C. 247b-4 and 42 U.S.C 241, respectively) (Appendices A1, A2, and A3).

A.2. Purpose and Use of the Information

The primary purpose of the proposed focus groups is to gain an understanding of the barriers to participation in the collection of biological specimens by mothers on themselves, infants, and young children. The key factor we want to analyze is the difference between biologics participators and non-participators. Secondly, we are trying to determine the reason for lower

participation rates among African-American women. Gaining an understanding of the barriers that non-participants face may lead to implementation of strategies that increase participation rates. An increase in participation ultimately will increase the power and validity of studies, such as the NBDPS, that collect biological specimens with less than optimal response rates. In addition, we plan to identify acceptable alternative methods of cell collection that will increase DNA yield, which will also make these studies more powerful.

The proposed data collection will consist of six well-designed focus group discussions to assess the attitudes of both mothers who have participated and mothers who have not participated in the collection of biological specimens for the NBDPS. All women who will participate in the proposed focus groups have already participated in the NBDPS computer assisted telephone interview (CATI). Thus, all women who will participate in the focus groups have shown an interest in study of birth defects. Two focus groups will include African-American women who participated in the collection of biologic material. Two focus groups will include African-American women who did not participate in the collection of biologic material. One focus group will include women of all races/ethnic groups who had low birthweight infants (<2,500g) and were biologics participants. One focus group will include women of all races/ethnic groups who had low birthweight infants (<2,500g) and were biologics non-participants.

Funding for the proposed focus group data collection will be provided by CDC through Collaborative Initiative intramural funding. Scientists from the NCBDDD, NCCDPHP, and OGDP have received funding to conduct focus groups aimed at gaining insight into the barriers and motivations women have for participating in the collection of biological specimens. One

limitation to this study is the inability to conduct more than six focus groups with the available funds, and as a result, the focus groups cannot be separated for as many factors as we would like to study. Although Spanish-speaking Hispanics and less-educated Caucasians have been identified as being among the lowest biologicals participators in the NBDPS at the Atlanta site, we chose to select the African-American population for this set of focus group discussions due to limited financial resources for the supplemental data collection and the desire to conduct more than one focus group for each segment of the identified population. If the opportunity arises to add more focus groups to the project, it would be beneficial to conduct focus groups with other populations having low participation in the collection of biological specimens.

A.3. Use of Information Technology and Burden Reduction

To reduce the burden on respondents, a tape recorder will be used to collect information from respondents during the focus group discussion sessions. Recording the focus group discussions reduces burden by eliminating the need for participants to write down their responses, thus shortening the discussion time. There are no other appropriate technologies to reduce burden in this setting.

A.4. Efforts to Identify Duplication and Use of Similar Information

A number of studies, including focus group discussions, have been conducted to analyze the attitudes of minority populations toward medical and genetic research (Singer et al 2004, Shavers et al. 2002, Furr 2002, Schulz et al 2003, Wong et al. 2004). These studies indicate that there are diverse ethnic concerns about participation in medical and genetic research, including concerns by all minority populations regarding potential discrimination based on population-

specific genetic risk factors for disease and a lower level of trust of all medical research among the African American population. The reluctance of African Americans to participate in medical research has been well documented over the last decade. Despite the fact that more than 30 years have passed, the legacy of the Tuskegee Syphilis Study remains a source of distrust and fear among African Americans with regard to participating in research studies (Freimuth et al 2001). Numerous researchers, advocates, and ethicists have also identified factors such as attitudes and beliefs about research in general, health care providers, and the Federal government as a whole as significant barriers to African American participation in research (Corbie-Smith et al 1999; Freimuth et al 2001). Decreased participation of African Americans in medical research may adversely affect efforts to address disparities in health status and limit the ability of research findings to benefit them.

Despite these well-documented concerns about scientific research in general, a review of the current literature revealed very little information available on participation of African-American women of childbearing age in studies that involve collection of biologic materials. Specifically, there are no studies that examine the cell collecting preferences of women who are asked to collect cells on themselves and their infants or young children. This study would help fill the existing knowledge gap.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses are or will be involved in this study.

A.6. Consequences of Collecting the Information Less Frequently

There are no legal obstacles to reduce the burden. However, if the proposed focus groups are not conducted, we will not have an evidence base with which to improve and target our recruitment efforts for the NBDPS.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The project fully complies with all of the guidelines of 5 CFR 1320.5.

**A.8. Comments in Response to the Federal Register Notice and Efforts to Consult
Outside the Agency**

8A. 60-Day Federal Register Notice

The 60-day notice was published in the *Federal Register* on March 17, 2006, Vol. 71, No. 52, pp 13852-13853 (**Appendix K**). One non-substantive public comment was received.

8B. Consultation Outside the Agency

A contractor, Westat has been retained to recruit, schedule, and conduct the focus group discussions. During the past 10 years, Westat has conducted more than 400 focus groups for CDC at 50 different locations nationwide. As a result, Westat has conducted focus groups with a wide range of populations, including African American women, mothers in particular. They have provided input into the development of the focus group protocol and will provide experience using rigorous, systematic methods to analyze focus group data.

The Westat point of contact is:

Erika Reid Gross, MA
Project Director
WESTAT Atlanta

2971 Flowers Road South
Oglethorpe Building, Ste 214
Atlanta, GA 30341
770-455-4897
ErikaReed-Gross@Westat.com

Additional consultants on this project included:

Christine Prue, PhD
Behavioral Scientist
Centers for Disease Control and Prevention
National Center on Birth Defects and Developmental Disabilities
1600 Clifton Road, NE
Mailstop E-86
Atlanta, GA 30333
404-498-3837 phone
404-498-3550 fax
cprue@cdc.gov

Patricia Mersereau, MSN
Division of Birth Defects & Developmental Disabilities
National Center on Birth Defects and Developmental Disabilities
Centers for Disease Control & Prevention
1600 Clifton Road, NE
Mailstop E-86
Atlanta, GA 30333
404-498-3871
PGM5@cdc.gov

A.9. Explanation of Any Payment or Gift to Respondents

[Our goal in providing an incentive to participants is to ensure adequate response rates for the focus group discussions. Focus group discussions will be held in the evenings during the work week. Women recruited for the discussions have young children, some with special health care needs, who will require childcare. High fuel prices and large commute distances in Atlanta make travel costs a potential barrier to participation. In order to increase response rates and promote equitable representation by potentially removing barriers to participation such as childcare and travel costs, an incentive is being provided that is meant to overcome these potential barriers.](#)

Pilot testing of the draft moderators' guides was completed in December 2006 with six eligible case mothers. Most of the mothers were paying for childcare and one of the mothers reported being unable to participate without provisions for transportation. All six mothers reported being "happy" or "pleased" to receive the incentive. Five of the six case mothers previously participated in the collection of biological specimens for the NBDPS ("biologics participators") and one mother did not participate in the collection of biological specimens for the NBDPS ("biologics non-participator"). Our goal for the qualitative study is to assess the attitudes of both biologics participators and non-participators toward collection of biological specimens. The lack of participation in the pilot test discussions by biologics non-participators is potentially a critical issue for the regular focus group discussions. The pilot test discussions included only case mothers, whereas the regular focus group discussions will include both case and control mothers. Based on previous participation rates, it is expected that recruitment of control mothers will be more difficult. Since focus group data is not generalizable, we rely heavily on the quality of recruitment for equitable representation. Including incentives that will overcome potential barriers to participation provides a greater and more equitable level of participation and allows collection of high quality data.

~~The total compensation to focus group participants will include a \$50 money order sent to them prior to the focus group discussion to cover childcare costs since all participants are mothers of young children, \$50 cash at the facility, and \$20 for travel if they choose to arrange their own transportation. Otherwise, access to pre-paid round-trip taxicab service, likely at a greater cost to the government, will be provided.~~

We propose to offer incentives to respondent for the following reasons:

Research into the Effects of Incentives:

The biggest impediment to conducting quality focus group discussions is low participation. We recently completed an NBDPS pilot study aimed at increasing participation in the cheek cell collection phase of the study that involved an additional \$20 incentive once the kits were

received at CDC (OMB Modification approved 12/30/2004). We observed an increase in participation, particularly among hard to reach populations. In non-Hispanic Black women, participation increased from 31.7% to 46% with the additional incentive (OR = 1.82; 95% CI: 1.22, 2.78; Crider et al 2006). The timing of the incentive (following return of a completed cheek cell collection kit) is believed to be the primary factor leading to increased biologicals participation rates following the additional incentive. [A study was conducted to test the effect of remunerating sample persons who participated in the National Health and Nutrition Examination Survey I \(NHANES I\). The response rate for those who were told they would receive remuneration was 82%. The response rate for those who were not told they would receive remuneration was 70%. Results of the study were published as "A Study of the Effect of Remuneration Upon Response in the Health and Nutrition Examination Survey, United States," Vital and Health Statistics, Series 2-No.67.](#)

Improved Coverage of Specialized Respondents, Race Groups, or Minority Populations:

Two thirds of the women who will be recruited to the proposed focus groups are African American, and one third are mothers (of all races) of low birth weight infants. Moreover, all women being recruited have young children. Since focus group facilities in the Atlanta area no longer offer onsite childcare due to liability and newly implemented state regulations (Georgia requires the facility to be licensed for childcare if a certain number of children are in attendance and requires a specific ratio of providers to children), we will provide a childcare stipend of \$50. The average rate for childcare in the Atlanta metro area is approximately \$10.00 per hour (Bureau of Labor Statistics, Appendix N, page 27). The focus groups will last approximately 2½ hours. Travel to and from the focus group facility including attending to childcare issues is

expected to take up to 2½ hours. Thus, childcare will be required for 5 hours (5 hours x \$10/hour = \$50.00). It is unlikely that women with young children would be able to participate in focus group discussions that require approximately 5 hours of their time on a weeknight without child care and a child care stipend.

Burden on the Respondents:

There is a substantial time burden on respondents to attend the focus group discussions. The focus group discussion will be presented as taking approximately 2 ½ hours of the respondent's time, approximately 2 hours for the discussion and approximately 30 minutes for paperwork, getting settled, and responding to any participant questions at the conclusion of the discussion. The average hourly wage in the Atlanta area is \$20.23 (BLS, Appendix O, page 2).

Participants will also incur costs as they travel to and from the focus group facility. Access to a scheduled, pre-paid round trip taxicab service will be provided at actual cost. Alternatively, a \$20 transportation stipend (courtesy ride, public transportation, mileage or a combination thereof) will be provided for those who wish to arrange their own transportation. Because of child care arrangements, there is no way of knowing commute times and distances for potential participants. According to www.cleanaircampaign.com/about-us/for-the-press/press-kit, the average commute in metro Atlanta is 29.2 miles. Because the focus groups will be held during the work week and all participants will have young children, they will likely have to commute farther than they typically would to attend to after-hours child care arrangements. Also, although the focus group facility is accessible by public transportation, we do not know how accessible the potential participants' residences are by public transportation. Many may require

taxicab service to the bus or subway. Due to the high cost of fuel, time of day for travel, and amount of traffic in the metro Atlanta area, a scheduled, pre-paid round trip taxicab service will likely cost in excess of \$20 for many focus group participants. Thus, the least costly method may be providing the transportation stipend.

Past Experience:

According to Mid-Atlanta Research, the focus group facility we will be using, it is standard in market research to offer cash payments to all focus group or interview participants. The payment is a gratuity which enables the research to be conducted. Mid-America Research has recently provided \$50 cash to diabetic patients interviewed for 75 minutes and \$100 cash to diabetic educators interviewed for 75 minutes. Sixty-six percent of focus group participants surveyed in a study by Rodgers Marketing Research in Canton, Ohio indicated compensation as the main motivator to participation (Krueger 1994). The primary function of the incentive is to get the participants to show up for the focus group – and to show up on time (Krueger, 1994). In order to increase participation in the supplemental focus group study, we plan to provide a monetary incentive of \$50 to focus group participants in appreciation of the time burden on them to attend the focus groups. This amount is in line with other focus group studies in the literature (Bates et al 2005, Mofitt 2004), and those conducted by Westat, including “Cultural Values and Norms and Their Influence on Parenting Attitudes, Beliefs, and Practices,” in which participants were compensated \$50 for participation and \$25 for transportation. [To maximize response rates to the examination, National Health and Nutrition Examination Survey \(NHANES\) participants are remunerated for their examination participation at a level of \\$100 and up to \\$40 for](#)

[transportation. If participants hire a sitter to care for children, elderly, or handicapped persons, they are provided with additional funds \(OMB number is NCHS 0920-0237\).](#)

Finally, to reward timeliness, participants arriving 15 minutes prior to the scheduled start time of the focus group discussion will be offered a chance to receive an additional \$25. This type of incentive has been used effectively by Westat in previous focus groups to allow discussions to begin on time. One participant per focus group will receive the additional \$25 incentive for timeliness.

A.10. Assurance of Confidentiality Provided to the Respondents

The CDC Privacy Officer reviewed this submission and determined that the Privacy Act does not apply to the proposed focus group activities. Although full names of respondents will be used by two project contractors (Battelle and Westat) to support focus group recruitment, scheduling and moderation, the full names of focus group participants will not be known to CDC. Additionally, response data compiled by the contractor from the focus group discussions will not be identifiable. The safeguards for respondent privacy implemented by each contractor are described below.

Battelle personnel will be responsible for the initial telephone contact with prospective focus group participants and for obtaining their permission to release participant names and contact information for follow-up. As previously noted, focus group participants will be recruited from the respondent universe for the National Birth Defects Prevention Study (NBDPS). Battelle personnel are currently involved in the NBDPS and comply with the NBDPS Certificate of

Confidentiality, which includes provisions for physical security of identifiable data as well as study-specific policies and procedures for maintaining respondent confidentiality. Battelle personnel associated with the NBDPS sign a Confidentiality and Data Use Oath, and will only release the names of prospective focus group participants to Westat after obtaining each individual's permission. Appendices B and C support this process. Identifiable contact information will be sent from Battelle to Westat via Fed Ex in a confidential carrier.

Westat personnel are responsible for the focus group scheduling and consent processes (**Appendices D, E, F, and G**) and will moderate the focus group discussions (**Appendices I and J**). Because the focus group activities will be covered by the existing Certificate of Confidentiality for the NBDPS, Battelle and Westat will implement procedures previously established for safeguarding respondent identity in the NBDPS. These procedures are outlined below:

1. Battelle staff will sign the NBDPS Confidentiality and Data Use Oath (**Appendix M**).
2. Westat personnel associated with the supplemental focus group study will also sign the confidentiality oath (**Appendix M**). Westat personnel will not release respondent identifiers to CDC or any other entity or individual.
3. For recruitment purposes, the CDC will send Battelle encrypted emails containing study IDs of previous NBDPS participants who may be considered potential focus group respondents.
4. Battelle will send Westat contact information of participants who agreed to release that information to Westat in a confidential carrier via FedEx.

5. Westat will provide a phone number dedicated to this study. This dedicated telephone line will serve as a communications safeguard as well as a convenience to callers.
6. Westat will only maintain respondent names and contact information as long as necessary to schedule focus group participation. Respondent identifiers and contact information will be destroyed as soon as practicable after participation in a focus group is confirmed.
7. Focus group discussions will be recorded by a voice recorder and a note taker.

Respondents will be asked to identify themselves only by first name. If a respondent inadvertently discloses her last name, it will be deleted from the project record. The audiotape and transcript of the focus group discussion cannot be linked to the scheduling information that contains the respondent's full name. Transcripts and notes obtained from the focus group discussions will be locked in a secure location at the Westat office. Only Westat project staff members are allowed access.
8. Westat will summarize the information from the transcript into a final report for CDC. The final report will contain only aggregated information and will not identify respondents, even by first name.
9. A Westat scheduler will be on-site to administer the Focus Group On-Site Screener (**Appendix H**) and to collect signed consent forms. The scheduler will not observe or take part in conducting the focus groups. The scheduler will leave the facility, taking all personally identifiable information with her, once all participants have checked in. No other Westat staff (observers, note-takers, moderator) will have access to the last name of the discussion participants. As required by the focus group management company to gain access to the facility, the Westat scheduler will provide a list of participant names. The management company will verify the identity of each participant by asking for photo

ID. This entry requirement ensures that only scheduled participants gain entrance and is not used in the disbursement of incentives. The management company will be the only entity that views the participant list and compares with photo ID. Following the check-in process, this list will be destroyed. Employees of the management company will not observe the focus group discussions.

10. The moderator is highly skilled and will emphasize not only the voluntary nature of the entire focus group discussion but the participant's prerogative to not answer specific questions. In addition, there are several instances before the focus group discussions take place where the participants are informed that their participation is voluntary: the initial contact telephone script (**Appendix B**), the letter from Battelle following the initial contact that includes a refusal form (**Appendix C**), the telephone script for the Westat scheduler (**Appendix D**), the introductory letter (**Appendix E**) and the informed consent form (**Appendix F**). The consent process also describes the safeguards for respondent privacy.
11. Focus group information will be protected under the Certificate of Confidentiality for the National Birth Defects Prevention Study, which serves as the basis for the proposed focus group supplement (see **Appendix A**, expiration 08/31/2009). The Certificate of Confidentiality, by preventing study staff from being forced under a court order or other legal action to identify study participants or provide individually identified data, supplies additional assurance to both participants and CDC's contractors that the data collected will be kept confidential and will not be subject to potential release from a wide variety of sources. Because the topics of the study are sensitive, respondents are more likely to

participate since they are assured their identity is secure and will not be subject to review by people outside of the research process.

12. The proposed supplemental data collection has been reviewed and approved by the CDC IRB as an amendment to the original NBDPS (**Appendix L**).

A.11. Justification for Sensitive Questions

Focus group participants will be asked a number of questions regarding their reasons for participating or not participating in biologic sample collection. Some focus group participants will have children with birth defects, and this may increase their sensitivity to some questions.

Potentially sensitive discussion questions include:

“How did you feel about being asked to collect a cheek cell sample?”

“What were some of your reactions when you first opened the kit?”

“What were the main reasons you decided to participate in the study?”

“What are some reasons that you would refuse to share genetic information?”

“ How did the money you received in your kit help you make the decision to collect cheek cells?”

These questions are necessary to the core purposes of the focus group study, i.e., understanding the barriers and motivations for participation in studies that involve collection of genetic material.

Moreover, to ensure that focus groups are segmented as described in the study methodology, information about focus group respondents’ Race and Ethnicity will be obtained from the

NBDPS as part of the pre-screening process. There will be no additional questions about Race and Ethnicity, which may be viewed as sensitive by a portion of respondents.

A.12. Estimates of Annualized Burden Hours and Costs

A.12.A Battelle will initially contact 180 potential participants by telephone to ask for permission to release contact information to Westat. Since we expect a 35% refusal rate at this stage, 117 women will receive the initial letter. These 117 women will read this letter and determine whether or not to complete and send in the no-contact form. We expect that approximately 23% of the women who receive the letter will send in the no-contact form, leaving 90 women to be scheduled for a focus group discussion. We expect 20% of the women scheduled for a focus group discussion will not show up (no-shows). Therefore, we expect a total of 72 women to participate in the focus group discussions. The focus group discussion will take approximately 2 ½ hours (2 hours for discussion the remaining time for paperwork, getting settled and any follow up questions from participants at the conclusion of the discussion.) Therefore, the burden for the focus group discussion is 180 hours (72 women x 2 ½ hours = 180 hours).

Table A.12-A. Estimates of Annualized Burden Hours

Type of Respondent	Form Name	No. of respondents	Number of responses per respondent	Avg. burden per response (in hours)	Total burden (in hours)
Focus group Participants	Focus Group Moderator’s Guide	72	1	2.5	180
Total					180

A.12.B The estimated annualized cost to respondents is \$3,641.40.

Table A.12-B. Annualized Cost to Respondents

Type of Respondents	Form Name	Total Annual Burden (in hours)	Average Hourly Wage Rate	Respondent Cost
Focus group participants	Focus Group Discussion	180	\$20.23	\$3,641.40
Total		180		\$3,641.40

The average hourly wage rate is based on the average hourly wage in the Atlanta area (\$20.23, BLS, Appendix O, page 2). There are no costs to respondents other than their time.

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers

There are neither (a) total capital and start-up costs, nor (b) operation, maintenance, and purchase of services costs for respondents or record keepers resulting from the collection of information.

A.14. Annualized Costs to the Federal Government

The total cost to the government is \$106,679. Of the overall annualized cost, 95.7% is contractor costs and fees (primarily data collection and analyses) totaling \$67,679.00. Three percent of contractor costs are collected as part of administrative fees assessed by CDC’s Office of Communication and the National Institutes of Health.

Table A.14-1: Estimates of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Costs* (dollars)
Direct Costs to the Federal Government	CDC Project Officer	\$2,500
	CDC Principal Investigator	\$5,000
	Contractors working on-site at CDC*	\$3,250
	Administrative Fees	\$3,250
	Subtotal, Direct Costs to the Government	\$14,000
Contractor and Other Expenses	Westat Contractor Cost and Fees	\$67,679
	Battelle Contractor Cost and Fees (subject tracing, contacting, follow up, materials, postage)	\$25,000
	Subtotal, Contracted Services	\$92,679
TOTAL COST TO THE GOVERNMENT		\$106,679

***These contractors work for Battelle, but they are on-site at CDC and complete work at CDC beyond the proposed data collection. Thus, their costs are direct costs to the government and are not included in the Battelle Contractor Cost and Fees.**

A.15. Explanation for Program Changes or Adjustments

This is a program change to address recruitment issues for the NBDPS.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Focus group data collection will begin in the winter of 2006 and will continue through February of 2007. Westat will produce a final report of the focus group findings that includes an executive summary, background of methods and findings as well as recommendations and implications. This final report will be available to all project collaborators 6 months following the conclusion of the focus groups.

A.16 - 1 Project Time Schedule

Activity	Time Schedule
Data Collection	December 2006 – February 2007
Data Analysis	March 2007 – August 2007
Final Report	September 2007

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

Expiration dates are displayed, so no exemption is sought.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions are sought.

B. Collection of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

The focus group discussion participants will have completed the NBDPS interview no more than two years prior to the focus group discussions. They will be separated by those who completed and returned the cheek cell collection kits (biologics participators) and those who never returned the kits (biologics non-participators). In addition to the biologics participation status, the mother's race, as well as the baby's birth weight will also be used to stratify the focus groups. There will be a total of six discussion groups: two will include African American women who are biologics participators, two will include African American women who are biologics non-participators, one will include women of all races/ethnic groups who had low birth weight infants (<2500g) and were biologics participators, and one will include women of all races/ethnic groups who had low birth weight infants (<2500g) who are biologics non-

participators. Although segmentation by biologics participation status restricts recruiting and scheduling, it is the primary variable we would like to analyze. All NBDPS participants received thank you letters that contained the statement, “we hope that we may feel free to contact you again, if, as we progress in our work, any new questions arise”. For this supplemental study, women can choose to participate or not to participate. Thus, they will be asked again to give informed consent.

Due to the restricted criteria for inclusion in the focus groups, it is likely that the study sample for recruitment will include all women from the designated two years of the NBDPS who meet the following criteria, and not a subset of women. The mothers recruited for this project will be both case and control mothers who 1) completed the computer-assisted telephone interview (CATI) portion of the NBDPS and 2) received a cheek cell collection kit, and 3) are English-speaking. Women eligible to participate in the focus group discussions will be selected based on information in the NBDPS CATI, clinical, and biologics databases. The women must have completed the telephone interview in English no more than 24 months before being recruited to the focus group. Mothers of deceased children will be excluded from this study to avoid putting them in a situation of potential emotional distress (i.e., participating in a focus group with mothers of small children). Before contacting the mothers, we will cross reference the National Death Index (NDI) to reduce the chance of contacting mothers of deceased children. Death records are added to the NDI annually, approximately 12 months after the end of a particular calendar year. Since we will not identify recent deaths using the NDI, Battelle recruiters will ask mothers for their child’s current age during the initial telephone conversation to sensitively

identify mothers of deceased children. The information will be recorded and mothers of deceased children will not be contacted again.

As indicated in section A.12, Battelle will initially contact 180 potential participants (30 women for each group) by telephone to ask for permission to release contact information to Westat. Since we expect a 35% refusal rate at this stage, 117 women will receive the initial letter. These 117 women will read this letter and determine whether or not to complete and send in the no-contact form. We expect that 23% of the women who receive the letter will send in the no-contact form, leaving 90 women to be scheduled for a focus group discussion. We expect 20% of the women scheduled for a focus group discussion will not show up (no-shows). Therefore, we expect a total of 72 women to participate in the focus group discussions.

B.2. Procedures for the Collection of Information

Since the success of a focus group depends on the willingness of participants to share their thoughts and opinions, focus groups typically rely on purposeful sampling techniques; that is, relatively homogeneous groups of people with something in common that is relevant to the topic of study (Krueger 1994). The more participants feel that they have in common with each other, the more comfortable they will feel in discussing the topic of study. Thus, homogeneity is critical to ensuring an open and permissive environment in which participants can discuss the topic at hand (Krueger 1994).

Despite its many advantages, focus group methodology has limitations. Findings from focus group discussions are neither quantifiable nor generalizable to the population as a whole – the

unit of analysis is the group, not the individual. We learn from the shared elements and patterns across groups and gain answers to the question of why something happens, rather than how often or how many. As a qualitative research tool, focus group methodology therefore does not lend itself to the rules often dictated by quantitative analytical techniques – “there are no rules for determining significance” (Patton 2002). In addition, “outliers” and more solitary voices have weight in focus group research and it is often the more uncommon views that are the most revealing and significant of findings. Minority viewpoints often take on significance in the analysis as possibly telling insights that warrant further analytic attention. Thus, it is not uncommon for focus groups to uncover issues for further study.

Collaborators at Battelle Memorial Institute in North Carolina will provide initial telephone contact with prospective focus group respondents to explain the qualitative research study and request the release of the respondent’s contact information to the project team at Westat (**Appendix B**). Battelle is currently responsible for interviewing women for the NBDPS that are part of the Atlanta Center for Birth Defects Research and Prevention (CBDRP) so they have had previous contact with all mothers being recruited. If the mothers agree to release their contact information, Battelle will provide their name, address, phone numbers, and biologics participation status to Westat by FedEx in a confidential carrier.

A contractor, Westat, has been retained to recruit, schedule, and conduct the focus group discussions. Westat will provide experienced recruiters, schedulers, moderators, note takers, audiotape equipment and operators, top line reports, audiotapes, transcripts, and transcript coders. The same moderator will conduct each focus group discussion. The moderator is an

African-American woman with more than 20 years experience facilitating focus groups. She will use the moderator's guides to direct the conversation but will allow freedom of discussion.

Following the respondent's consent to release contact information, Battelle will send her a letter that contains further information about the qualitative research study, including the amount and types of compensation that will be provided (**Appendix C**). In addition to a participation stipend of \$50, a childcare stipend of \$50 will be provided since all women being recruited have young children, and a \$20 transportation stipend (courtesy ride, public transportation, mileage) or access to a scheduled, pre-paid, round-trip taxicab service will be provided at actual cost. The letter will also include a form that can be completed and returned within 10 days of receipt in a prepaid return envelope stating that she no longer wishes to be contacted about the qualitative research study. If no form is received 14 days after mailing the initial letter, the Westat scheduler will place a telephone call to the respondent to confirm her intent to participate and to schedule her focus group discussion.

After scheduling the focus group discussion, the Westat team will send the respondent a packet that includes a \$50 money order to cover childcare costs. The packet will also include a consent form (**Appendix F**), appointment card, information about taxi service if requested, directions to the focus group facility and a phone number to reach the scheduler in case it is necessary for her to cancel. Westat will establish a dedicated telephone number to be used exclusively for this study. The Westat scheduler will place a reminder call two days before and the morning of the respondent's scheduled focus group discussion (**Appendix G**). The contractor will ask her if she needs round-trip taxicab service. If so, the scheduler will arrange for a taxi to pick her up and

take her to the focus group facility.

The six focus group discussions will be held over a two-to-four week timeline at a facility near Lenox Mall in Atlanta, a location that is accessible via public transportation. The focus group discussions will be held on weekday evenings with one discussion each evening. Thirty women will be recruited for each group with the expectation that 50% of the women will decline to participate. Fifteen women will be scheduled for each focus group, with the expectation that twelve (80% of those who are scheduled) will attend the discussion. Women who schedule an appointment and do not come to the discussions will not be recontacted. The number of women included in each focus group discussion will range from a minimum of 3 to a maximum of 12. If fewer than 3 women arrive at the focus group facility, they will be compensated for their time, given a transportation stipend, and the focus group discussion will be rescheduled. If more than 12 women arrive at the focus group facility, the women in excess of 12 will be compensated for their time, given a transportation stipend, and asked to leave but can be added to another focus group discussion if they agree and if the appropriate focus group type is available. If between 3 and 6 women arrive at the focus group facility, the discussion will proceed but an additional make-up discussion with another group of women will be scheduled. The focus group discussions will be presented as taking 2 ½ hours of the participant's time, approximately 2 hours for the discussions and the remainder for paperwork, getting settled, and any questions from participants at the conclusion of the discussion. Westat will conduct an onsite re-screen to verify the correct group assignment (**Appendix H**). The screening tool will include 2-4 questions that will include confirmation of child's age and biologics participation status.

Moderator guidelines for biologics participators (**Appendix I**), and biologics non-participators (**Appendix J**) have been developed and the objectives of each are summarized below.

<p align="center"><u>Moderator Guidelines Objectives for Biologics</u> <u>Participators</u> <u>(Appendix I)</u></p>	<p align="center"><u>Moderator Guidelines Objectives for Biologics</u> <u>Non-Participators</u> <u>(Appendix J)</u></p>
<p>1. <i>To determine general feelings participants have about genetic testing. Since all participants completed the first portion of the study (the interview), we want to determine whether participants had decided whether they would complete biologics before agreeing to complete the interview or whether their decision regarding biologics participation was a direct result of their interview experience.</i></p>	<p>1. <i>[Same as for Participators]</i></p>
<p>2. <i>To determine what changes can be made to the cheek cell sample kit or to the incentive amount to help increase biologic participation. To determine if receiving the kit from an institution other than the government would increase biologics participation.</i></p>	<p>2. <i>[Same as for Participators]</i></p>
<p>3. <i>To determine what changes could be made to the materials included in the cheek cell sample kit to make the collection easier to understand or to communicate that the samples need to be returned quickly with or without the father sample. To determine the reasons mothers may wait to return their samples. Is collecting the father sample a barrier to participation?</i></p>	<p>3. <i>To determine at what point the participants decided not to complete the cheek cell sample kit. To determine if participants attempted to collect samples but never returned them. Were they waiting on the father, felt like too much time had passed...?, Should information be added to communicate that samples need to be returned quickly with or without the father sample? To determine what changes could be made to the materials included in the cheek cell sample kit to make the collection easier to understand.</i></p>
<p>4. <i>To determine if there is an alternative to cheek cell collection using cytobrushes (blood, saliva, mouthwash) that mothers would</i></p>	<p>4. <i>[Same as for Participators]</i></p>

<p><i>prefer for themselves, their child, or their child's father. To determine the feelings mothers have toward supervised collection methods (those that include a health care provider). To determine if collecting samples from the father is a barrier to participation.</i></p>	
---	--

Samples of all introductory and follow-up material that is sent to NBDPS participants will be available for respondents to examine during the focus group discussions. To stimulate discussion and respondents' ability to recall their reasons for participating or not participating in the cheek cell collection, example cheek cell sample kits will be available for all respondents to look at throughout the discussion. The example kits will each include an example of the letter, consent form, cheek cell collection instructions, return envelope, and three colored envelopes with wrapped brushes inside. If a participant expresses interest / volunteers to complete a kit for the NBDPS, the moderator will provide an address where it can be sent. The moderator will not ask discussion participants to complete kits. The moderator will have sets of cards that contain pictures of different methods used to collect biologic material. The moderator will explain the research method portrayed on each card and will ask the mothers to sort the first set of cards according to the likelihood that they would participate in that method of research. The mothers will be asked to sort a second set of cards according to the likelihood that they would allow their child to participate in that method of research. Finally, the mothers will be asked to sort a third set of cards according to the likelihood that the child's father would participate in that method of research. The moderator will quickly determine how the group ranked each card using a tally system. Following the tally of all cards, the group will discuss advantages and disadvantages of each research method beginning with the card that was most frequently placed on top. To save

time, the ordered cards will be collected by a Westat staff member, tallied and recorded following the focus group discussion.

At the end of the focus group discussions, the participants will be asked to call the phone number dedicated to this study in case they think of something they would like to add after the focus group discussion is complete or if they want further information about the focus groups or the study. Additionally, reference material about support groups for families of children with birth defects will be available at the discussion facility for the mothers to take with them.

B.3. Methods to Maximize Response Rates and Deal With Nonresponse

Contact information for prospective respondents is at most 2 years old, and should be relatively current. Advance calls and letter clearly inform prospective respondents about the purpose of the focus groups. An opt-out response card is included as a courtesy. Reminder calls will be placed by scheduling staff to reduce number of respondents who forget time or location of meeting. Other conveniences associated with scheduling include the availability of taxi service, and the dedicated telephone number that facilitates communication with the scheduler and the ability to reschedule. An incentive plan that offsets the respondents' time and expenses for participating is clearly stated. A facility in north-central Atlanta that is accessible by public transportation and that is located in close proximity to several dining options will be used. Privacy protections are included and made clear to the participants.

A professional moderator having more than 20 years experience facilitating focus groups among African American women will be used. She will use the moderator's guides to direct the conversation but will allow freedom of discussion.

Finally, as justified in section A9, focus group discussion participants will receive \$50 in appreciation of their time and effort. In addition, a childcare stipend of \$50 will be provided since all women being recruited have young children, and a \$20 transportation stipend (courtesy ride, public transportation, mileage) or access to a scheduled, pre-paid, round-trip taxicab service will be provided at actual cost.

B.4. Tests of Procedures or Methods to be Undertaken

Westat will pilot test the moderator's guides by conducting an in-person interview with one or two mothers representing each of the participant segments. An in-person interview is necessary to allow evaluation of the card sorts. The pilot testing participants who complete the in-person interview using the moderator's guide will receive the same remuneration as described for the actual focus groups.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Mary Jenkins, PhD
Health Scientist & NBDPS Biologics Coordinator
Division of Birth Defects & Developmental Disabilities
National Center on Birth Defects and Developmental Disabilities
Centers for Disease Control & Prevention
1600 Clifton Road, NE, Mailstop E-86
Atlanta, GA 30333
404-498-3889
MQJ2@cdc.gov

Margaret A. Honein, PhD, MPH
Epidemiologist & Principal Investigator, NBDPS
Division of Birth Defects & Developmental Disabilities
National Center on Birth Defects and Developmental Disabilities
Centers for Disease Control & Prevention
1600 Clifton Road, NE
Mailstop E-86
Atlanta, GA 30333
404-498-3921
MRH7@cdc.gov

Sarah Ruuska, MPH
NBDPS Project Coordinator
Division of Birth Defects & Developmental Disabilities
National Center on Birth Defects and Developmental Disabilities
Centers for Disease Control & Prevention
1600 Clifton Road, NE, Mailstop E-86
Atlanta, GA 30333
404-498-3931
SRR9@cdc.gov

Sonja Rasmussen, MD, MS
Medical Geneticist
Division of Birth Defects & Developmental Disabilities
National Center on Birth Defects and Developmental Disabilities
Centers for Disease Control & Prevention
1600 Clifton Road, NE, Mailstop E-86
Atlanta, GA 30333
404-498-3908
SKR9@cdc.gov

Cindy Moore, MD, PhD
Medical Officer
Office of Genomics and Disease Prevention
Centers for Disease Control & Prevention
1600 Clifton Road, NE
Mailstop K-89
Atlanta, GA 30333
770-488-8397
CAM0@cdc.gov

Wanda Barfield, PhD
Epidemiologist
National Center for Chronic Disease Prevention and Health Promotion

Centers for Disease Control & Prevention
1600 Clifton Road, NE
Mailstop
Atlanta, GA 30333
617-624-6084
Wanda.barfield@dph.state.ma.us

Peg Gallagher, PhD
Microbiologist
National Center for Environmental Health
Centers for Disease Control & Prevention
4770 Buford Hwy, Mailstop F-24
Atlanta, GA 30341
770-488-3612
MXG2@cdc.gov

Alison Woomert, PhD
Project Leader
Center for Public Health Research and Evaluation
Battelle Memorial Institute
100 Capitola Drive, Suite 301
Durham, NC 27713-4411
909-544-3717
Woomert@battelle.org

Chris Prue, PhD
Behavioral Scientist
Division of Birth Defects & Developmental Disabilities
National Center on Birth Defects and Developmental Disabilities
Centers for Disease Control & Prevention
1600 Clifton Road, NE, Mailstop E-86
Atlanta, GA 30333
404-498-3837
cprue@cdc.gov

Patricia Mersereau, MSN
Division of Birth Defects & Developmental Disabilities
National Center on Birth Defects and Developmental Disabilities
Centers for Disease Control & Prevention
1600 Clifton Road, NE, Mailstop E-86
Atlanta, GA 30333
404-498-3871
PGM5@cdc.gov

References

- Bates, BR, Lynch, JA, Bevan, JL, Condit, CM. (2005). Warranted concerns, warranted outlooks: a focus group study of public understandings of genetic research. *Soc Sci Med*, 60, 331-344.
- Corbie-Smith, G., Thomas, S., Williams, M., Moody-Ayers, S. (1999). Attitudes and beliefs of African Americans toward participation in medical research. *J Gen Intern Med*, 14, 537-546.
- Cozier, YC, Palmer, JR, Rosenberg, L (2004). Comparison of Methods for Collection of DNA Samples by Mail in the Black Women's Health Study. *Ann Epidemiol*, 14, 117-122.
- Crider, KS, Whitehead, N, Buus, RM. (2005). Genetic variation associated with preterm birth: A HuGE review. *Genet Med*, 7(9), 593-604.
- Crider, KS, Reefhuis, J, Woomert, A, Honein, MA. (2006). Racial and Ethnic Disparity in Participation in DNA Collection at the Atlanta Site of the National Birth Defects Prevention Study. *Am J Epidemiol*, epub July 28, 2006
- Freimuith, V., Quinn, S., Thomas, S., Cole, G., Zook, E., Duncan, T. (2001). African Americans' views on research and the Tuskegee Syphilis study. *Social Science and Medicine*, 52(5), 797-808.
- Furr, LA. (2002). Perceptions of Genetics Research As Harmful to Society: Differences among Samples of African-Americans and European-Americans. *Gen Testing*, 6(1), 25-30.
- Garcia-Closas, M, Egan, K, Abruzzo, J, Newcomb, P, Titus-Ernstoff, L, Franklin, T, Bender, P, Beck, J, Le Marchand, L, Lum, A, Alavanja, M, Hayes, R, Rutter, J, Buetow, K, Brinton, L, Rothman, N. (2001). Collection of genomic DNA in epidemiological studies by buccal cytobrush and mouthwash. *Cancer Epidemiol. Biomark, Prev.*, 10, 687-696.

- Giarratano, G. (2006), Genetic influences on preterm birth. *MCN Am J Matern Child Nurs*, 31(3), 169-175.
- Krueger, RA (1994). *Focus Groups: A Practical Guide for Applied Research*, 2nd edition. Thousand Oaks, CA Sage Publications.
- Le Marchand, L, Lum-Jones, A, Saltzman, B, Visaya, V, Nomura, AMY, Kolonel, LN, (2001). Feasibility of Collecting Buccal Cell DNA by Mail in a Cohort Study. *Cancer Epidemiol. Biomark. Prev.*, 10, 701-703.
- Lynberg, MC, Khoury, MJ. (1993). Interaction between epidemiology and laboratory sciences in the study of birth defects: design of birth defects risk factor surveillance in metropolitan Atlanta. *J Toxic Environ Health*, 40, 435-444.
- Moffitt, R. (2004). Three-City Study Incentive Experiment: Results from the First Two Waves. Downloaded from <http://www.jhu.edu/~welfare>.
- Ng, DP, Koh, D, Choo, S, Chia, KS. (2006). Saliva as a viable alternative source of human genomic DNA in genetic epidemiology. *Clin Chim Acta*, 367(1-2), 81-85.
- Patton, M.Q. (2002). *Qualitative Evaluation and Research Methods*, Third Edition, Thousand Oaks, CA: Sage Publications, pg. 433.
- Schulz, A, Caldwell, C, Foster, S. (2003). "What Are They Going to Do With the Information?" Latino/Latina and African American Perspectives on the Human Genome Project. *Health Education & Behavior*, 30(2), 151-169.
- Shavers, VL, Lynch, CF, Burmeister, LF. (2002). Racial Differences in Factors that Influence the Willingness to Participate in Medical Research Studies. *Ann Epidemiol*, 12, 248-256.
- Singer, E, Antonucci, T, Van Hoewyk, J (2004). Racial and Ethnic Variations in Knowledge and Attitudes about Genetic Testing. *Gen Testing*, 8(1), 31-43.

Svensson, AC, Pawitan, Y, Cnattingius, S, Reilly, M, Lichtenstein, P. (2006). Familial aggregation of small-for-gestational-age births: the importance of fetal genetic effects. *Am J Obstet Gynecol.*, 194(2), 475-479.

Wong, ML, Chia, KS, Wee, S, Chia, SE, Lee, J, Puay Koh, W, Ming Shen, H, Thumboo, J, Sofjan, D. (2004). Concerns over Participation in Genetic Research among Malay-Muslims, Chinese and Indians in Singapore: A Focus Group Study. *Community Genet*, 7, 44-54.

National Birth Defects Prevention Study

OMB 0920-0010 Supplement Application

List of Appendices

- Appendix A1** Public Health Services Act, Section 317C (42 U.S.C. 247b-4)
- Appendix A2** Public Health Services Act, Section 301 (42 U.S.C. 241)
- Appendix A3 Birth Defects Prevention Act of 1998**
- Appendix A4** Certificate of Confidentiality for the National Birth Defects Prevention Study
- Appendix B** Telephone script for initial contact and request for permission to release contact information
- Appendix C** Letter following initial contact
- Appendix D** Telephone script for focus group scheduler
- Appendix E** Focus group letter
- Appendix F** Focus group consent form
- Appendix G** Telephone reminder script
- Appendix H** Focus group on-site screener
- Appendix I** Moderator Guide: Biologics Participators
- Appendix J** Moderator Guide: Biologics Non-Participators
- Appendix K** 60-day Federal Register Notice
- Appendix L** CDC IRB approval for focus groups
- Appendix M** NBDPS Confidentiality Oath
- Appendix N** Bureau of Labor Statistics Atlanta Wage Table (Childcare Estimate)
- Appendix O** Bureau of Labor Statistics Atlanta Wage Table