

Final Report

National Children's Study Focus Groups- Follow-Up

Prepared for:

Danelle T. Lobdell, Ph.D.
U.S. Environmental Protection Agency
National Health and Environmental Effects Research Laboratory

Prepared by RTI International under contract 68-D-02-069:
Linda L. Dimitropoulos, Ph.D.,
Carol Prindle, Ph.D.

RTI Work Assignment Leader: Linda L. Dimitropoulos, Ph.D.

RTI International
6110 Executive Boulevard, #420
Rockville, MD 20852
Telephone: (301) 230-4691
Fax: (301) 230-4647
E-mail: emarks@rti.org

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Prepared for:

EPA Work Assignment Manager: Danelle Lobdell, Ph.D.

Attn: Ms. Frances Legg
U.S. Environmental Protection Agency
RTP-Procurement Oper. Div (D143-01)
4930 Old Page Road
Durham, NC 27709

Prepared by:

RTI Work Assignment Leader: Linda L. Dimitropoulos, Ph.D.,
Carol Prindle, Ph.D.
RTI International
203 N. Wabash, Suite 1900
Chicago, IL 60601
Telephone: (312) 456-5246
Fax: (312) 456-5250
Email: lld@rti.org

RTI Contracting Specialist: Kelly Koeller-Anna
Office of Research Contracts
Research Triangle Institute
P.O. Box 12194
Research Triangle Park, NC 27709-2194
Telephone: (919) 316-3746
Fax: (919) 316-3911
E-mail: kellyk@rti.org

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Executive Summary

The National Children's Study Focus Groups represent an effort to learn more about the factors affecting recruitment and retention in a longitudinal cohort study of national scope. This series of 14 focus groups, comprised of pregnant women and parents of young children, was designed to gather the opinions and beliefs of a diverse set of individuals representing a cross-section of racial and ethnic minority groups in the US about participation in the NCS. There is an established literature that cites mistrust of medical research and health care providers as a significant barrier to participation in medical research (Corbie-Smith, Thomas and St. George, 2002; Corbie-Smith, Thomas, Williams, and Moody-Ayers, 1999; Roberson, 1994). The main goal of this work was to bring together the members of eight racial and ethnic minority groups to discuss issues that they felt would be barriers to their participation in the NCS. The groups were designed to be comprised of 7 to 9 participants representing the following racial/ethnic groups: African-Americans, non-African-American Blacks, Mexican-Americans, non-Mexican-American Hispanics, American Indians (2 groups), and Asians (2 groups). In addition to issues related to race and ethnicity, the study called for conducting two groups with pregnant teens and teen parents and two groups with couples who were trying to become pregnant. Finally, two groups comprised of pregnant women and parents of young children were convened to explore in greater detail, issues related to the collection of biological samples.

RTI and EPA developed selection criteria for the groups to increase the likelihood that the members of each group shared a similar cultural background but also increased the differences between the groups. All groups were comprised of pregnant women or the female parents of young children (11 or younger). The only exception was the groups of couples for which we recruited male/female pairs. Because many of the topics could be considered sensitive in many cultures and would not be openly discussed in mixed company, a decision was made to limit the groups to women with the obvious exception of the two couples' groups.

The African-American group included women who were African-American but not of Hispanic descent. The non-African-American Black group was comprised of non-Hispanic black women who self-identified as being black but not of African-American descent.

The two Hispanic groups included one group of Mexican-American women who were Spanish-speaking and one group of non-Mexican-American Hispanics such as Puerto Ricans, Cubans, and Central and South Americans who were conversant in English. The Mexican-American group was conducted in Spanish and the non-Mexican-American group was conducted in English.

The composition of the Asian groups took into account some historical animosities and cultural differences. For example, the Chinese and the Japanese have strong cultural differences as do Koreans and Japanese, and Pakistanis and Indians. If members of the group are too different they may be less likely to speak about their own cultural beliefs which could shut down the discussions in the groups. Based on these considerations, we decided that one group should be comprised of women from Chinese

and Vietnamese descent and one group could be comprised of women who are Filipino-South Asian Indian-Indonesian.

The challenge with the composition of the American Indian groups was how to maximize the quality and diversity of ideas discussed in the two groups given the large number of tribes living in the US. Discussions about the best way to constitute the American Indian groups were held with a number of Native American organizations and American Indian groups including the Seattle Indian Health Board, United Indians of all Tribes Foundation, the American Indian Health Commission for Washington State, the All Indian Pueblo Council in Albuquerque and Native American Management Services (NAMS). We decided that we would work through two firms: one in Seattle and one in Albuquerque to recruit two diverse groups of American Indians drawing from both urban dwellers and those who live on reservations. The American Indian groups in these areas generally get along well enough that we believed that mixing would not be a problem.

For the groups of teens, couples and women discussing biospecimens, we attempted to recruit a diverse group of pregnant women or parents of young children. Teens between the ages of 15 and 19 who were currently pregnant or a parent were recruited in New York and Illinois where their status allows them to consent to participate in research. The couples were male/female pairs who were attempting to become pregnant and the only selection criterion for women recruited for the biospecimen discussion groups was that they be pregnant or the parent of a young child.

The groups were conducted at six different sites across the country. Sites were selected based on the geographic distribution of the racial/ethnic groups and the availability of appropriate and cost-effective facilities with experience conducting ethnic research with these populations. Sites selected included New York, Chicago, Research Triangle Park, Albuquerque, Seattle, and Los Angeles. Recruiting for the groups was conducted by RTI and four firms that specialize in ethnic research.

The group discussions were varied. Some groups talked a great deal and other groups were very reserved. There were a number of common themes and some widely divergent beliefs. There were four main topic areas:

- How do we get you interested?¹
- What about the time commitment and the data collection activities?
- How do we keep you interested?
- Barriers to participation

How Do We Get You Interested?

All of the groups mentioned their doctor's office as the place they would want to learn information about the NCS. The groups offered many suggestions for additional places and ways to

¹ The guide for the biospecimen groups was modified to allow more time for discussion of the biospecimen collection so the first topic section those groups discussed was a brief "orientation to the study."

disseminate the information about the study. The groups also agreed on the kind of information they would want to have before they would contact the study and consider participation. This includes:

- Purpose of the study
- Details about participation
- Risks and benefits of participation

The benefits that participants would like to see as a result of their participation ranged from the knowledge that they were making a contribution to society to hoping to find out why their child is ill. The groups were somewhat excited about being part of a national study but did not want to feel like they were being used as research subjects. The groups thought a spokesperson would be good, but it would have to be someone with credibility and who was a parent. The groups did not think that the person had to be a celebrity but at least one group noted that if the spokesperson was not someone they were familiar with they would think it was just a model or an actor in a commercial. The Surgeon General was the most recommended person.

What About the Time Commitment and Data Collection Activities?

Number of Office/Home Visits. Overall, the groups thought that the plan for participation that was presented was reasonable if the early childhood visits were added onto the regular well-child visits. The groups also recommended using a portion of the blood or urine collected at regular visits for the study to reduce the invasiveness of the specimen collection. Other concerns included transportation to and from visits and whether the participants would incur any costs for the visits.

Collection of House Dust and Tap Water Samples. Most participants preferred someone come to their homes to collect water and dust samples. They were reluctant to agree to use the kits to collect the samples themselves because they did not want to make any mistakes. Others were willing to use the kits if they could be trained and have easy-to-read instructions. If someone is to come to their home they want advance notice and the person should have the appropriate identification. A few participants were concerned that study staff would make unscheduled home visits to evaluate their parenting skills or their living conditions.

20-Minute Survey. All participants agreed that a 20-minute survey 2 or 3 times in a year was reasonable. Groups were mixed in terms of which mode they would like to use to complete the survey—mail, phone, or email. Here again they wanted flexibility in the form of a choice of modes.

Biologic Specimens. Reactions to the collection of the various biological samples were quite varied. There was widespread agreement that they would need to know exactly why the tests were being performed and what would be done with the results before agreeing to provide specimens. Some participants would also want to know how the samples would be stored and disposed of. There was some concern that the specimens might be used for drug testing or by the government to build a DNA data base to be used in criminal investigations. There was also concern that specimens or results might be released to an entity outside of the study such as an insurance company.

Most focus group members would agree to provide samples of their own urine and blood and would allow the collection of urine and blood from their children if the procedures were minimally invasive. The only group that voiced an objection to giving blood was the Chinese-Vietnamese Asian group. Some participants said that blood was “precious” as the source of life and that giving blood would make them feel faint and they would then need to eat a couple bowls of rice to recoup their energy. The group also noted that some Asian women have small veins and it is difficult and painful to provide blood samples.

When asked whether they would agree to allow testing on the placenta reactions were varied with most people agreeing as long as they knew what the test were and would receive the results. Many noted that it would be thrown away anyway. The American Indian women however noted that the placenta is sacred in their culture and it is used in a ceremony to protect the child. Giving up the placenta would violate tribal tradition.

The collection of umbilical cord blood was not an issue for most of the women. Some participants noted that they would want to store cord blood for future use and had interest in stem cell research if it would benefit their children.

Most participants were willing to provide breast milk samples. A few women mentioned that they did not breast feed their babies. Some of the teens thought it would be too painful.

There were no objections to providing the meconium samples and few objections to providing fingernail clippings and buccal cells. However, the notion of providing hair samples and baby teeth was met with some resistance. The objections to collecting hair samples ranged from the practical (e.g., children have very little hair or very short hair) to the supernatural (e.g., use of hair in Voodoo and witchcraft rituals) to the legalistic (e.g., DNA samples could be used in criminal investigations or drug testing). The objection to the collection of baby teeth was sentimental value. Most of the mothers in the groups said that they would not give up the baby teeth, at least not the first tooth.

Genetic Testing. The majority of participants had some knowledge of genetic testing but clearly this was not a well-understood topic. Even so most participants agreed to genetic testing under certain conditions. They wanted to be insured of the confidentiality of the results and they wanted to be certain that the results were not provided to anyone other than their health care provider. A major concern was that the information would be provided to insurance companies who would use the information to deny future coverage.

Consent/Assent by Child. Participants were asked at what age the child should sign his or her own consent form. Almost all participants thought that the appropriate age would be 18. However, the ages mentioned ranged from 11 to 21 with several participants saying that the age at which the child is capable of understanding and taking responsibility varies from child to child.

How Do We Keep You Interested?

Discussions of incentives for participation were lively. Almost all group participants believed that they should receive some kind of incentive for participating. However, most participants were adamant that information obtained from physical examinations and testing would not be an incentive but rather something that they would expect as participants in the study. Most of the groups thought that gifts for both the child and the parent were appropriate. Gifts to children should be age appropriate and should stay current with the times. One group thought that incentives should be greater in the first year because the demands on time were greater but most groups thought that gifts should increase the longer you are in the study.

Gifts as Incentives. Focus group members had clear likes and dislikes regarding gifts. On the low end, group members preferred gift certificates to coupons because they did not have to put up any of their own money. Group members especially liked gift certificates to national chain stores such as Wal-Mart. Participants were not interested in certificates for child photos and preferred gift certificates or money for school supplies or clothing rather than toys. Participants also proposed other gifts for the children including tickets to events, payment for classes, books, camp or field trips for the child, and membership in clubs. Generally, focus group members were not interested in cable TV subscriptions, Internet access or Web-TV. Many thought that electronic equipment would be appropriate gifts for older children. On the high end, most of the groups suggested college tuition, savings bonds, or IRAs for the child. Some parents wanted health care coverage. In part reflecting their dependence as teen parents, one of the teen groups wanted very basic needs to set up a household such as Section 8 housing or rent vouchers, furniture, a stove or refrigerator, and clothing.

Monetary Incentives. When asked if money was an appropriate incentive most groups agreed that it was indeed appropriate and welcome. There was no overall consensus as to whether gifts or money would be appropriate in return for biological specimens. Some participants were eager to develop a price list and a few others noted that it seemed like they would be “selling” their child.

Focus group members generally preferred cash for themselves and gifts for the children. Most participants recommended an incremental payment schedule. There was no agreement on the amounts that would be appropriate for the study to pay. Amounts that were mentioned included \$50 to \$100 per visit and \$200 to \$500 per year. At the end of the study most participants wanted a big payoff-- IRA, savings bond, or college tuition account.

Most focus group members said that none of the incentives discussed would make them feel that they were being coerced or had no choice about their participation unless the incentive was really large. If the incentive was too large they might feel uncomfortable or suspicious. But they were generally unable to say what amount would be too large. Some focus group members expressed the concern that if the gifts were too large, they study might become bankrupt and shut down. A few other participants suggested getting corporate sponsors to provide gifts.

Keeping Informed About the Study. Participants were asked a series of questions about how the study can keep them informed. Most participants wanted their own personal test results to come to them in a private and secure way (such as personalized mail or a password protected web site) or directly from the doctor. They indicated that they wanted to receive personal test results immediately after each visit to the doctor so that they could take action if there is a health problem. Participants also wanted to be provided with general study progress and findings in periodic newsletters or via a study web site. Although some participants mentioned monthly and annual updates of study information, most preferred to receive this information quarterly or every 6 months.

Most of the participants reacted to the question about whether there was any information that they would not want to receive by saying that they want to receive all information. The participants did not want to feel that the study was hiding something from them. Most participants wanted the results of all of their tests even if the results cannot be interpreted at this time.

Part 4: Barriers to Participation

While most focus group participants said they would agree to participate in the NCS if given the opportunity, some may have objections to participating in individual components of the study such as providing some of the biologic specimens. Participants said that they would want reassurance that the study was a legitimate effort with enough support to be able to achieve its goals. Participants also noted that they would want clear, concise communications with study staff. They want to be able to trust that what they are agreeing to when they consent to participate is true and accurate. Several participants wanted assurances that the data would be used for the right purposes and that it would not “fall into the wrong hands.” Many participants were specifically concerned about drug testing or that genetic information might be put into a data base or given to insurance companies. Some participants feared that later in life the child would be stigmatized if there was a genetic problem.

When asked what the NCS could do to address their concerns, focus group participants suggested making certain that all details of the purpose of the study are explained in the potential participant’s native or primary language at enrollment. This would include a full explanation of the costs and benefits of participation and how their information would be protected. The data collection schedule and methods used should be flexible so that participation is as convenient as possible. Many participants noted that they want to be treated as a partner in the research. They would like consistency in staffing so that they would have contact with the same staff over time to allow them to develop a rapport. Participants would also feel more comfortable if they could be seen by their primary physician for office visits and specimen collection.

1.0 Introduction

The purpose of this work assignment was to add to our knowledge of the issues that will affect recruitment and retention of pregnant women into the National Children's Study by conducting 14 focus groups comprised of pregnant women, couples, and parents of young children who represent a range of racial and ethnic minority groups. Eight of the groups conducted were comprised of women recruited from eight different racial and ethnic groups. Four of the groups were devoted to issues affecting pregnant teens, and couples trying to conceive, and two groups focused only on the collection of biologic specimens. The information collected from this set of focus groups expands on the information gathered from an earlier series of 18 focus groups conducted with five major stakeholders in the NCS—pregnant women, parents of young children, parents of children with disabilities, community representatives and health care providers.

Based on information learned in the early groups and on an extensive literature on mistrust of researchers among racial and ethnic minorities, we wanted to explore further the ways that beliefs about mistrust of research, particularly medical research, and institutional racism may impact recruitment and retention of racial and ethnic minorities into the NCS. Another area of concern involves the special issues and circumstances that are specific to pregnant teens. It will be important to know what this group thinks about committing to participate in the NCS. Since the NCS plans to enroll women into the study as early in pregnancy as possible, a third important group included couples who are trying to conceive. Would this group have unique concerns about enrolling in the NCS? Finally, we were interested in learning more about how women think and feel about the collection of biologic specimens both during pregnancy, delivery and from the child after birth. This topic was covered in the previous 18 focus groups but only as one topic among many. In this set of focus groups, the collection of specimens was the main topic of discussion that allowed us to explore the topic in depth.

This report describes the findings from fourteen focus groups that were comprised as follows:

- Pregnant teens and teen mothers (2 groups)
- Couples currently attempting to become pregnant (2 groups)
- Pregnant women and parents discussing biologic specimen (2 groups)
- Pregnant women and mothers of varied racial and ethnic backgrounds (8 groups)
 - African-American, (non-Hispanic)
 - Non-African-American Black (non-Hispanic)
 - Mexican-American
 - Hispanic (non-Mexican-American)
 - Native American Pacific Northwest
 - Native American Southwest
 - Chinese-Thai-Vietnamese Asian
 - Filipino-South Asian Indian-Indonesian

This report also provides an overall summary of the major themes that emerged from both the earlier set of 18 focus groups and the 14 focus groups conducted in this follow-up.

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2.0 Method

The National Children's Study Focus Groups represent an effort to learn more about the factors affecting recruitment and retention in a longitudinal cohort study. This series of 14 focus groups comprised of pregnant women and parents of young children was designed to further investigate some issues raised in the previous work and to explore issues raised during planning discussions for the NCS. The groups were limited to a maximum of nine participants in accordance with the work assignment.

In addition to issues related to race and ethnicity, the study called for conducting two groups with pregnant teens and teen parents and two groups with couples who were trying to become pregnant. Finally, two groups comprised of pregnant women and parents of young children were convened to delve into issues related to the collection of biological samples.

2.1 Composition of Groups

Selection criteria were developed to reduce overlap between the groups and to prevent mixing members of groups that have traditional, historical animosities. The main criteria for selection were that participants be pregnant women or parents of young children (11 or younger). The African-American group was comprised of women who also self-identified as being of African-American descent but who did not self-identify as Hispanic. The non-African-American black group was comprised of non-Hispanic black women who self-identified as having an ethnicity other than African-American. This group could include West Indians such as Jamaicans and Haitians, Africans, and Black women from other countries.

There were two Hispanic groups. One group was comprised of Mexican-Americans and one comprised of non-Mexican-Americans such Puerto Ricans, Cubans, and Central and South Americans. The Mexican-American group was conducted in Spanish and the non-Mexican-American group was conducted in English. The rationale for this approach was that women who are more comfortable speaking in Spanish or who do not speak English may have some different ideas and beliefs than women who are either native English speakers or who have been speaking English comfortably for a long time.

Consideration of some significant historical animosities and cultural differences was raised when deciding on the composition of the two Asian groups. For example, the Chinese and the Japanese have historical animosities, as do Koreans and Japanese, and Pakistanis and Indians. If members of the group are too different they may be less likely to speak about their own cultural beliefs which could shut down the discussions in the groups. Based on these considerations, we decided that one group should be comprised of women from Chinese and Vietnamese descent and one group could be comprised of women who are Filipino-South Asian Indian-Indonesian.

2.2 Site Selection

There were two main factors that affected site selection: geographic distribution of the racial/ethnic groups and the availability of appropriate and cost-effective facilities with experience conducting ethnic research with these populations.

The 2000 US Census shows that about half of the Asian population in the US lives in the West followed by the Northeast. Over half of all Asians live in 3 states: California (by far the largest), New York and Hawaii. Cities with a population of over 100,000 that have the largest Asian populations are New York, Los Angeles, and Chicago. There are larger numbers of South Asian Indians in New York City than Los Angeles, and more Vietnamese in Los Angeles than New York. Based on review of the Census, we decided to conduct the South Asian Indian-Filipino-Indonesian group in New York and the Chinese-Vietnamese-Thai group in Los Angeles.

In addition the US Census records show that subgroups of the Hispanic population are distributed in a number of areas with Mexicans concentrated in larger numbers in the West, especially in California, Texas, and Arizona. We decided to conduct the Mexican-American group in Los Angeles and the non-Mexican-American group in New York City where there are concentrations of people from Puerto Rico, Cuba and South America.

Discussions about the best way to constitute the American Indian groups were held with a number of individuals and organizations representing American Indian groups including the Seattle Indian Health Board, United Indians of all Tribes Foundation, the American Indian Health Commission for Washington State, the All Indian Pueblo Council in Albuquerque and Native American Management Services (NAMS). We decided that we would work through two firms: one in Seattle and one in Albuquerque to recruit two diverse groups of American Indians drawing from both urban dwellers and those who live on reservations. The different American Indian groups in these areas generally get along well enough that we believed that mixing would not be a problem.

The decision to conduct the two teen groups in New York and Chicago was based on the relative ease of finding organizations that support pregnant teens to facilitate recruiting and because these states allow for the teens to consent for themselves to participate in the groups.

Although we did not restrict the recruitment of couples who are trying to become pregnant to those who were seeking medical assistance to conceive, we reasoned that it would be easiest to recruit couples trying to conceive in areas where there are fertility clinics. We decided to conduct these groups in RTI's facilities in RTP and in Chicago; both are sites with numerous medical centers and clinics. RTI facilities were also used to host the groups that would discuss the collection of biologic samples. Conducting some of the groups in the RTP office had the added advantage that it allowed EPA to observe some of the groups firsthand. **Table 1** shows the distribution of focus groups across sites.

2.3 Recruiting

The recruiting task was split between focus group facilities that specialize in conducting research with racial and ethnic minority groups and RTI recruiters. As indicated in *Table 1*, all of the racial and ethnic minority groups and one of the teen groups were recruited by facilities screened and hired by RTI and all other groups were recruited by RTI recruiters.

Table 1. Sites Selected for the Focus Groups

Group	Site	Group
1	Los Angeles	Mexican-American
2	Los Angeles	Chinese-Vietnamese
3	New York	non-Mexican-American Hispanic
4	New York	non-African-American Black
5	New York	Filipino-S. Asian Indian-Indonesian
6	New York	Pregnant teens and teen parents
7	Seattle	American Indian
8	Albuquerque	American Indian
9	RTI-Chicago	Pregnant teens and teen parents
10	RTI-Chicago	Couples trying to become pregnant
11	RTI-Chicago	Biologic specimen group
12	RTI-RTP	African-American
13	RTI-RTP	Couples trying to become pregnant
14	RTI-RTP	Biologic specimen group

2.3.1 Recruiting by Focus Group Firms

RTI selected focus group recruiting firms that specialize in ethnic research to recruit all of the racial/ethnic minority groups except the African-American group which was conducted at RTI's North Carolina facility. Each of the selected firms maintains a large database that is used as a starting point for recruiting potential participants. The staff at each firm contacted households in their existing databases that were most likely to contain expectant mothers (households with women between the age of 18 and 45) and parents of children under 12 years of age in the target racial/ethnic groups and young women age 15 to 19 for the teen parent group that was conducted at a focus group firm. Two firms—those in New York and New Mexico—also used community-based recruiters. In addition, the firms recruited participants by contacting community organizations (especially those that serve particular racial/ethnic groups), posted flyers in places where the target groups frequent, and advertised in local newspapers.

RTI provided each firm with the appropriate screening materials for each group to ensure that participants met the required racial/ethnic/national origin criteria or other criteria. RTI also provided these firms with recruiting forms, flyers, and confirmation letters. All materials were IRB approved. For the Mexican American group, RTI provided Spanish language screeners and other materials.

The firms were tasked with recruiting a mix of pregnant women and mothers of children under 12 years of age for each group. The firms were to try to achieve some diversity within each group among the participants in their age, educational level, annual household income, number and age of children, and urban/suburban/rural residence. In addition, no participant was to be recruited who had been involved in another focus group in the last six months and that no two participants in any group should be related with the exception of the groups comprised of couples.

During the recruiting effort, the firms provided daily updates on the number of recruits, their pregnancy status, and their racial/ethnic/national origin. For the American Indian groups, we also requested tribal affiliation and whether the recruits lived on a reservation. RTI monitored the composition

of the groups to maximize diversity within their homogeneous definitions. All of the groups were diverse with respect to participant age, education, annual household income, number and age of children and residence. The American Indian groups were comprised of participants representing a range of tribal affiliations. In Seattle, there were participants representing ten tribal affiliations and in Albuquerque, six tribal affiliations were represented. Detailed descriptions of the composition of each group are included in the individual group summaries that follow.

2.3.2 Recruiting by RTI

RTI recruited participants for the Chicago and Research Triangle Park, NC groups by advertising in local newspapers, contacts with community organizations and health care providers, posting of flyers, and referrals by word-of-mouth. RTI staff recruiters were very knowledgeable about the local areas and had experience in recruiting participants for focus groups from these areas.

African-American Group

RTI recruited pregnant women and mothers of children under age 12 in the RTP area and held the group session at the RTI offices. RTI contacted local community organizations that serve the African-American community, including the Multi-Cultural Student Affairs Office and the University Art Museum (which specializes in African-American art) at North Carolina State University. RTI also placed ads in the Nubian Message, a student newspaper at North Carolina State University that serves the larger African-American community in the RTP area and the Independent Weekly. Recruiters contacted OB/GYN and pediatric practices, the Durham Health Department, the University of North Carolina Hospital, the Durham Regional Hospital, day care centers, and other community organizations like the Boys and Girls Club, and three YMCAs that serve all communities, including the African-American community. Recruiters also posted flyers in public places where all groups of people congregate, including area restaurants, three Parks and Recreation facilities, four grocery stores, a toy store, and a shopping center.

Pregnant Teens and Teen Mothers

RTI recruited one group of pregnant teens and teen mothers in Chicago and held the group session in the RTI facility. RTI recruiters contacted pregnancy centers, community health centers, and organizations that work with teenagers. Recruiters also contacted the following organizations: Planned Parenthood of Chicago; Supervised Independent Living Program (for teens); Metropolitan Family Services (which includes home visits to first time pregnant teens); the Ounce of Prevention Fund; Maternity Services (counseling for pregnant teens); Catholic Charities Arts of Living; and Birthright, Inc. These organizations were asked to post flyers and to tell their clients about the study. In addition, RTI posted flyers in the following locations: three local hospitals; eight colleges; three YMCAs; three offices of Women, Infants, Children (WIC); and eight community organizations. These community organizations included the Uptown Crisis Pregnancy Center, Aid for Women, Care First, Teen Living Program, Alivio Medical Center, National Runaway Switchboard, and the Chicago Children's Advocacy Center. RTI also advertised in the local free paper in Chicago, The Reader, to recruit this group.

Couples Trying to Become Pregnant

RTI recruited two groups comprised of couples trying to become pregnant, one in RTP and one in Chicago. For these groups both the female recruit and her partner needed to participate. The goal was to obtain a mix of couples who were receiving services from a fertility specialist and those who had not sought assistance.

The groups of couples were more difficult to recruit and schedule than the other groups. Based on some of the questions we received from inquiries about participation, potential participants viewed fertility as a private issue and were concerned that we would ask them to speak in the group about their personal experience. Thinking that this might be the barrier to participation, we modified the flyer used to recruit this group so that it was clear that the participants would discuss recruitment and retention issues related to the NCS, rather than their personal experience with trying to conceive. A second barrier to recruitment we found was that both members of the couples were generally both working and had very hectic schedules. Recruiters tried to schedule the groups to find times that both individuals could attend.

In Chicago, the group was rescheduled twice. For the first scheduled group, RTI had recruited only two couples. A few days prior to the group meeting, one couple cancelled because the woman was called in to substitute for a teacher who was ill and the other couple cancelled because the woman had to travel for work that day. The group was rescheduled and besides the two couples previously recruited; three more couples were recruited. One couple cancelled the day before the group was to meet and two couples canceled just a few hours before the group was scheduled to meet. One of the couples recruited initially cancelled because the woman and her partner both worked two jobs and no longer had time. Another couple cancelled because the company the man worked for was sold and they had a final management meeting that day. The third couple had to cancel because the woman missed a flight and would not arrive in time. The fourth couple just did not show up. The group went forward with the one couple who did attend. In RTP, the group was rescheduled twice to allow more time to recruit for this group. The group was ultimately conducted with four couples but the recruiting was very difficult.

The recruiters in RTP initially targeted fertility centers and OB/GYN offices. Recruiters called relevant organizations and asked them to post flyers. Recruiters contacted the Duke Fertility Clinic, Eastowne OB/GYN & Fertility clinic; Private practice physicians, the University of North Carolina Hospital; and women's health clinics such as Associates in Women's Healthcare and the Durham Women's Clinic; and Durham Health Department. These organizations agreed to post flyers. Recruiters also placed flyers in areas that young couples were likely to frequent like restaurants and movie theaters. Advertisements were also placed in the local free paper, the Independent Weekly.

In Chicago, recruiters contacted the Fertility Centers of Illinois, a fertility group called Karande and Associates; Chicago Gold Coast (center for human reproduction), Oak Brook Fertility Associates; the Advanced Fertility Center of Chicago; North Shore Fertility; Maternity Services Centers for Maternal and Fetal Health clinic at Evanston Hospital; Genetic Counseling Center for Maternal and Fetal Health at Evanston Hospital; and the Institute for Women's Health. In addition, RTI posted flyers at three colleges

(including the Northwestern University School of Medicine) and six hospitals, including Children's Memorial Hospital. RTI also advertised in the local free paper, The Reader.

Biospecimen Groups

RTI also recruited for two focus groups of pregnant women and mothers of young children to discuss the collection of biospecimens for the NCS. One group session was held at the RTI office in RTP and the other was held at the RTI office in Chicago. RTI recruited participants through telephone calls to local parent organizations, placing ads in a local newspaper and the posting flyers in areas likely to be frequented by pregnant women and parents of young children.

In RTP, recruiters contacted the following community organizations: John Avery Boys & Girls Club; three YMCAs; day care centers; and three Parks and Recreation Centers. In addition, RTI contacted several health facilities including the University of North Carolina Hospital, Durham Regional Hospital, the Durham Health Department, and Rex Health Care. Recruiters also put up flyers in public areas, grocery stores, a toy store, and a shopping center and advertised in the local free paper, the Independent Weekly.

In Chicago, recruiters contacted the following organizations: Homefirst Health Services; PEDIAGROUP Associates; Chicago Women's Health Center; Heartwood Center; Saint Elizabeth Hospital; North Shore Association for OB/GYN; Women's Health Specialists; Obstetrics & Gynecology Associates; Family and Child Development Center; Smart Love Parent Center; Birthways Inc.; Early Years Program; La Leche International; Parent's Circle; and Metropolitan Family Service. In addition, RTI posted flyers at one university and two schools. Recruiters also advertised in the local free paper, The Reader, to recruit this group.

Table 2 shows the locations and dates the focus groups were held, the number of recruits, and the number of participants who actually attended each of the groups.

2.4 Staffing and Training

RTI staffed moderators and, to the extent possible, note-takers who were from similar racial and ethnic backgrounds as the focus group participants. All staff participated in a one-day training at RTI headquarters in Research Triangle Park, NC. RTI staff prepared a training package that contained all the information that moderators and note-takers would need to prepare for, conduct, and summarize data from the focus groups.

RTI and EPA staff reviewed the moderator's guides for each group with the moderators and note-takers to insure that each question was understood, that the probes were clear, and that each moderator understood when to refer to the various presentation posters. In addition, staff were trained for all of the activities that needed to take place before and after the actual focus group discussion. For example, before the session, staff needed to assemble all the necessary materials (e.g., consent forms, incentive money, receipts, and posters). In RTP and Chicago this included making sure that the audio and

Table 2. Number of Recruits for the EPA National Children's Study Focus Groups Follow-up

City	Date	Group	No. Recruited	No. Attended
RTP	11/12 6-8pm	African-American	9	9
Chicago	11/12 7-9pm	Biospecimen	11	8
RTP	11/13 7-9pm	Biospecimen	8	7
Chicago	11/18 7-9pm	Teen	8	5
New York City	12/1 6-8pm	Non-Mexican-American Hispanic	11	6
New York City	12/2 6-8pm	Filipino-S. Asian Indian-Indonesian	11	7
New York City	12/3 6-8pm	Non-African-American Black	11	5
Chicago	12/3 7-9pm	Couples	5 couples	1 couple
New York City	12/4 6-8pm	Teens	11	9
Seattle	12/8 7-9pm	American Indian	10 (10 tribal affiliations)	7
RTP	12/9 7-9pm	Couples	4 couples	4 couples
Albuquerque	12/9 6-8pm	American Indian	12 (6 tribal affiliations)	9
Los Angeles	12/10 7-9pm	Chinese- Vietnamese	13	8
Los Angeles	12/11 7-9pm	Mexican-American	10	9

videotaping equipment was set up properly and participant refreshments were delivered. An important part of training was the consent process—reading the consent form; making sure that all participants understood and signed the forms; signing the forms as a witness; providing a copy to the participant, and collecting the original forms. Staff were also trained on post-discussion activities, including payment of incentives, signing and collecting receipt forms, collecting audio and videotapes, and, at focus group facilities, collecting participant screeners. The final part of training covered the process by which notetakers would take notes, review the tapes for quotes and draft summaries of key findings.

2.5 Analysis and Reporting

The primary data reported here has been drawn from the notes taken during each focus group supplemented by the audio and videotapes. The Spanish-language group tapes were transcribed and translated into English. This process of describing participants' answers to specific questions and distilling prevailing themes for each discussion group is the first level of data analysis. We did not perform data coding of the audio or videotapes.

The notes were reviewed by the notetaker and the moderator immediately following each group to be sure that all themes were captured. The notetakers then reviewed their notes against the videotapes to clarify the discussion and extract illuminating quotes. The notetakers also drafted the initial summary of their group discussion.

The reporting team then reviewed the summaries, notes and videotapes, as necessary to compile the report and make recommendations based on the information learned in each of the groups.

3.0 Focus Group Summaries

3.1 Racial and Ethnic Minority Focus Group Demographics

Demographic Characteristics	African-American RTP N=9	Non-African- American Black New York N=5	Asian New York N=7	Asian Los Angeles N=8	American Indian Albuquerque N=9	American Indian Seattle N=7	Non-Mexican- American Hispanic New York N=6	Mexican-American Los Angeles N=9
Age								
18-25	0	2	2	0	7	0	1	1
26-35	5	3	1	2	1	6	5	2
36-40	3	0	2	2	0	1	0	4
41 or older	1	0	2	4	1	0	0	2
Pregnant								
Yes	0	0	3	4	4	0	2	2
No	9	5	4	4	5	7	4	7
Number of Children								
None	0	0	2	0	1	0	0	0
1-2 children	8	4	5	6	7	5	5	7
3-4 children	0	1	0	2	1	2	1	1
5 or more children	1	0	0	0	0	0	0	1
Ages of Children*								
Less than 3 years old	3	4	0	1	3	3	2	1
3-5 years old	2	1	0	4	5	5	3	3
6-11 years old	5	2	5	5	2	3	4	6
Hispanic								
Yes	0	0	1	0	0	0	6	9
No	9	4	6	8	9	7	0	0
Missing		1						
Race**								
American Indian or Alaskan Native	0	0	0	0	9	7	0	0
Asian	0	0	7	8	0	0	0	0
African-American/ Other Black	9	5	0	0	0	0	0	0
Native Hawaiian or Pacific Islander	0	0	0	0	0	1	4	0
White	0	0	0	0	0	2	1	0
Refused							1	9
Missing								
Highest Grade or Year of School Completed								
Less than high school	1	1	0	0	2	0	0	1
High school graduate	1	0	2	3	4	0	1	6
Some college	4	4	2	2	3	6	4	2
College graduate	1	0	0	3	0	1	1	0
Graduate school	2	0	3	0	0	0	0	0
Total Annual Household Income								
\$10,000 or less	0	1	0	0	1	0	0	1
\$10,001 to \$30,000	1	1	4	1	8	1	3	7
\$30,001 to \$50,000	2	1	3	1	0	3	1	0
\$50,001 to \$75,000	1	0	0	3	0	3	2	1
\$75,001 to \$100,000	0	1	0	2	0	0	0	0
More than \$100,000	2	1	0	1	0	0	0	0
Don't know	2							
Refused	1							
Area of Residence								
Urban	3	5	7	8	5	2	6	9
Suburban	3	0	0	0	1	3	0	0
Rural	3	0	0	0	3	2	0	0

*Some women had children in more than one age group.

**Participants could select more than one race.

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3.1.1 African-American Focus Group Summary

The African-American group was held in the RTI focus group facility in RTP, North Carolina. Twelve participants were recruited, and nine attended. Five of the women were between the ages of 26 and 35; three of the women were between the ages of 36-40 and one woman was age 41 or older. The group was quite varied with respect to income and educational background. All were parents of young children. Four participants had children between the ages of 0 and 2; one participant had a child between ages of 3 and 5; and, four participants had children between the ages of 6 and 11.

Part 1: How Do We Get You Interested?

The group members suggested numerous places and methods that could be used to attract participant interest for the NCS. All agreed that a physician's office would be the number one choice. Two women suggested church, and the remaining 7 women nodded in agreement. One woman suggested that schools, such as PTA meetings, would also be a strong option, as this is where she learned of which physicians in the area to visit. Several of the women suggested advertising with social services/human services, at health fairs, and local community centers. All of the women agreed that advertising in local areas would be advantageous and recommended the local Wal-Mart or ads placed on billboards and buses. The group also agreed that radio announcements would be good. Another suggested that doctor's offices could play a message about the study in lieu of the music often played when on hold.

There was a consensus that certain media would not be useful for recruiting purposes. These included TV and mailed letters. One woman stated that "You do not get anything on TV." The women agreed that there must be something extremely eye-catching on an envelope to invite them to open it, as "People throw it in the trash." There was concern voiced by all of the women when asked whether a well-respected non-profit organization could attract participants because they believe many organizations are not legitimate. They did feel that organizations such as the NAACP, certain sororities, the Girl Scouts, and the Boy Scouts would have influence with participants as these are societies they are familiar with and respect the organization's mission.

Before agreeing to participate, the women agreed they would want certain pieces of information explained. The group was interested in the history of the program and how long it has been offered. The information that they wanted to have clarified included the purpose and requirements of the study including the time commitment. They also wanted to know if there would be any out-of-pocket expenses and if there was compensation and, if necessary, transportation. One woman summed it up by stating:

- "We want to know where, when, and why."

One woman suggested that an information session be held with all the possible participants within an area. Here an information package could be passed out giving details on the study's expectations. This would offer an opportunity for potential participants to ask questions following a presentation by the study team. All women agreed that a video should be provided for interested participants who either have no transportation or are unable to attend the session. One woman said she would attend the session if she were compensated. Another woman felt that attending the session should be optional as, "Some

cannot relate in big groups.” This woman said she would move at her own pace and probably would not watch a video or read an information packet all at once. All women agreed that a toll-free number should be available for study questions (This was a theme to be mentioned numerous times). The consensus of the group was that an information session would give everyone the opportunity to ask questions because,

- “We would all have a lot of questions.”

This group would be most interested in participating if they knew how the results of the study would be used. They would want to know what impact the study would have on the environment and the child, and what the goals of the project would be. One woman would not care if the study was very large and nationwide. Another woman disagreed and suggested that this would be an important factor that she would use to carefully map out on a flow chart the pros and cons of participating. She continued to explain that being able to see (graphically) where she and her child would fit into the sample design would be motivational.

When discussing the possibility of using a spokesperson for the NCS, two women suggested a pastor or religious person. When asked about whom they actually saw in this role, they changed to suggest other celebrity types. All agreed that Oprah Winfrey, a recognized child spokesperson, an animated character, a children’s character such as Barney (or the current favorite character, since these change), a basketball star, and Maya Angelou would be influential. The group did not think that the President of the U.S. would attract participants. They agreed that the spokesperson would not need to be African-American, but it should be someone who assists the African-American community or someone who is an outspoken advocate for children.

In response to the question that asked what would they would most like to get out of their participation, the group agreed that the information collected from their children be used to improve life conditions for others. It is important that “Whoever participates benefits from the study.” One woman reiterated this with “Please let us benefit from the service,” and all agreed. They would want to know that the study would help to change the environment of the child for the better. They would want to know that the study would continue to benefit the child as the child grows.

Part 2: What About the Time Commitment and Data Collection Activities?

After the women reviewed the planned number of doctor and home visits, the women agreed that the number of prenatal visits was acceptable even if the visits were in addition to their regular prenatal visits. One woman suggested that for the year between ages 1 and 2 there should be more frequent visits. Four women agreed there should be office visits every year and not every other year from age 7 through 21. One woman stated that there are “so many changes from year to year, they need at least once a year [visits].” Four women disagreed and felt that visits once every other year were preferable because they would not require additional time since most of the children receive a physical examination once a year.

The group shared a concern for families that do not have their own transportation to attend the doctor’s visits. Suggestions included a toll-free number to call to arrange transportation to a scheduled

appointment. One woman suggested that the study provide cab vouchers to families. The group also suggested transportation for the children once they become teens so that the parents would not need to miss work to transport their child to office visits. Eight women agreed that evening and weekend appointments would work best and that plenty of advance notice would be necessary.

All of the women agreed that a research team member visiting their home to collect tap water or house dust would be acceptable "As long as it is a scheduled visit..." One woman asked why they could not collect the samples themselves. This comment led to a discussion of how difficult it would be to collect the samples properly noting the possibility of reading sample collection instructions incorrectly. If they were to collect the samples using a kit, the women agreed that all needed materials must be included in the shipment and that the return shipment must be postage paid. Five women decided they would rather have a team member collect the samples for them. Many women felt the time of 1 hour for the home visit was too long (if only to collect samples). If the visit were once a year, perhaps the visit would only be 15 minutes. If the visit is only once every 2 to 3 years, the sample collector could be there for hours. One woman suggested having the home visit before the office visit to see if there are any effects of the child's immediate environment on their health. One woman who had initially been skeptical of the number of visits decided that if a participant chose to be included in the study, then they could not argue with the guidelines. The group agreed that the technician would have to have identification and would need an appointment.

- "As long as they have a badge and I know they are coming."

One woman stated that completing a 20-minute questionnaire by mail was acceptable. Three women preferred Internet surveys, and two women preferred telephone surveys. All women agreed that if completing the questionnaire by telephone, they would prefer to speak with a live person as opposed to an automated message. One member of the group has the "phone zapper" which disconnects computer/automated calls automatically. Automated calls could lead to hang-ups, unfinished questionnaires, and "zapped" calls. Also, it might be difficult to reach participants via the telephone as "People get amnesia" when called and forget that they agreed to be called for a study. All women agreed that the phone call should begin with a mention of an incentive. If sending the questionnaire by mail, there should be a large recognizable NCS logo on the envelope so the participant would not discard the letter. The group agreed that participants should have the option of what method they would prefer to use when completing the questionnaire. They also suggested that the questionnaire could be completed during the home/office visits. It might be advantageous to send a postcard or have a reminder call to alert participants to complete the questionnaire, with perhaps an incentive included.

All the women agreed it would be acceptable for the mother to provide urine and blood samples during the prenatal visits as "they do that for visits anyway." The women also agreed to allow the physicians to examine the placenta, the umbilical cord blood, and the meconium from their newborns. The women were curious to know what would be done with the placenta and raised the point that they do not know what hospitals do with placentas or what has been done with their placenta in the past. When

asked if they would provide breast milk, the response was agreeable but a little slower and quieter than previous requests. One woman finally replied, “Yeah, why not.”

When asked if they would object to doctors collecting urine and blood samples from their infants, all were agreeable as the physicians already collect these. An issue of which doctor would be collecting the samples arose. All of the women preferred that this would be through their primary physician with whom the child is already familiar, and that these samples be taken during regular checkups as opposed to special visits. They felt the children would be less fearful with familiar faces. One woman stated that “If it is not the same person, I do not let them give my baby shots.” Another woman said she would allow a physician in the same practice to perform the collection if their primary physician is absent, but only if she knows them as well. The women all agreed that it would be preferable if the physician’s office already had all the child’s information on file, including all the study records (this theme of interconnectedness of the primary physician with the study was to come up many times).

No one objected to having doctors collect samples of buccal cells, hair, and fingernails from the child but there were concerns about how the samples would be taken. One woman was concerned about the fingernails being cut too close to the skin. An issue of hair collection did arise. “How would they get hair from African-American boys who wear their hair very short?” The group suggested (and quickly dismissed) the idea of collecting the sample from the barbershop. Another woman suggested delaying the trip to the barber if a hair sample is needed. The group raised the issue of whether it would be possible to collect the hair from the underarms, pubic area, and off the arm of older children.

All of the women were very interested by the types of information that could be learned from tests conducted on the baby teeth. Once they were told that the teeth would be collected after they had fallen out, the women were a little more comfortable with the idea of providing baby teeth. One woman said that she would only throw them away and was fine with donating them to the study. Seven women had no objections to providing baby teeth. Two women were hesitant and one stated, “I’m laid back until you talk about the teeth!” She had just had her first child. There was a question of whether or not the teeth could be returned after testing was complete. The women all agreed they would want information on what kind of testing would be done on the baby teeth and how long the study would keep them (they felt this information would have to be provided for all samples taken).

The group was not familiar with the idea of genetic testing so newborn screening was provided as an example that might be familiar to the group. The group did not raise any specific concerns about genetic testing. However, they would want their child to be tested for numerous disorders, not just those that are most prevalent in African-Americans. They felt that everything should remain confidential. One woman asked what would be done if abnormalities were discovered. She would want to receive information on where to receive treatment as she would wish to be educated and not just notified of problems. All of the women agreed with this. The women suggested that the NCS send cards to let them know if any adverse test results were discovered. The women would also want the NCS to notify their primary care physician if there are any problems, so that when they call to make an appointment, their physician would already be aware of the situation. The women all agreed that they would want their

primary care physician to be connected to the study and that the study should be held responsible and accountable for coordination with the primary care physician.

There was a minor disagreement between group members over when the child should be able to sign the consent form without parental consent. One woman was thought that the child should be able to consent at age 17; seven women said that the child should not be able to consent until age 18. One woman would want to continue to sign the consent form with her child until the age of 21 as a way to keep the family-child bond.

Part 3: How Do We Keep You Interested?

When the women were handed the list of potential incentives, most found that nothing on the card really stood out as an attractive incentive. Coupons and gift certificates for kids' supplies must be age appropriate for the child, they said. The incentives should be updated as the child ages and as "society changes." One woman suggested there should be gifts for the parent as well. Another woman mentioned that savings bonds would be a very appropriate incentive that should be included on the hand card, and all the women agreed (this issue of savings bonds was to be reintroduced many times as an attractive incentive). The amount of the savings bond should increase as the child ages and could be put to many uses for the child.

Education was a key theme throughout this discussion and other suggestions for incentives included money for books, computer software and discounts on upgrades, and school supplies. One woman stated that the "Incentives should be useful, and not just toys." It was mentioned that free Internet would be useful to the parents, but could be dangerous for the children (because of all the perpetrators on the Internet). All agreed that they would not expect a very large incentive for such a little burden as 1 visit per year. The women also agreed that wealthy participants would not be attracted to the incentives listed on the hand card. Many in the group felt that feedback on the child's health was the most useful incentive. One woman summed it up by stating that there should be around 20 incentives to choose from because "Everyone doesn't need the same thing."

When questioned about incentives given for providing biological samples, the women agreed that less (expensive) incentives should be given. Many felt it was not necessary to give incentives for each sample given, as the greater incentive is the feedback. It was also mentioned that giving incentives for certain samples, such as teeth, might make a person more agreeable to providing the samples. Some women might attach more values to giving biological specimens and the study may need to give gifts for out of the norm requests. Eight women agreed that they do not want their child to grow up thinking they should be paid for doing a good deed. The women wanted to know if the incentives would be given annually. One woman stated that if the participant does not want the incentives, they should have the option of refusing to accept the incentive.

The women were agreeable to money being offered for participation, but that it should not be the main reason for participating. The study must be careful about the amount of money being offered, and be cautious about insulting participants with the amount offered. The women still agreed that savings

bonds would be preferable, but that these still need to be increased as the child ages, and that feedback itself would be a valuable incentive. If offering money, the amount needs to be comparable to the amount of time the family has committed. Again, for more wealthy families, the money might not be the main draw to the study. The general idea is that it would be difficult to quantify exactly how much money would be fair to offer, and that this amount would have to increase as the study continued.

The women understood that this is a voluntary study that participants would be able to leave at any time. Some felt that if they received a very expensive incentive, they may feel obligated to continue participation. There was also the mentioning of the possibility of the child deciding not to participate once they reach 18 and incentives may not be a satisfactory reason to continue with the study.

All of the women agreed that they would like to stay informed of project happenings via post cards, reminder cards (for appointments, etc), and information packets. The women again mentioned their dislike for telephone calls, unless there is a clear beginning statement identifying the study, and their dislike for automated messages. Again they mentioned that the letters must be eye-catching enough to jog their memory so they will not be discarded.

The women once again stressed their desire for ongoing feedback from the research team on the study results. They would not only want feedback once the study has been completed. They would want to have this information so that if the child's environment were adding to difficulties or creating problems, they could take proactive steps to correct this. In general, they would want the study to provide a service to the community, but they would also want a service provided to them.

All of the women would want to receive an update on what is being done with the data collected, and what is being done to improve the health and safety of the child. They would want to receive periodic reminders of how they are benefiting from the study to keep them interested in participating, and information on where to receive treatment for ailments that often affect African-Americans. The women would want to be able to call an 800-phone number if they have any health/environmental questions or problems with the child. They would want to know if something were found to be wrong with their child. But, they also need the study to be willing to provide answers on how to get help. The study must identify the problem, and help find the solution. There is no information concerning their child they would not want to receive.

Part 4: Barriers to Participation

The women agreed that there was nothing presented during the focus group that would prevent them from participating in the study. There were no specific concerns about participating in a large national study like the NCS. However, they want to be convinced of the benefits to the child and they would require enough detailed information to make this decision. All of the women agreed the NCS is appealing because it seems to be "upfront" (i.e., full disclosure of the plans and intent) and voluntary.

Where the women hear about the study will be the major influence on whether or not they perceive the study as legitimate and agree to participate. The group mentioned that since they do not trust

all non-profit research organizations, the NCS would need to be endorsed by a familiar organization such as the NAACP, or Girl Scouts.

The women also agreed that the NCS should develop plans for participants who do not have transportation and implement a toll-free number so that participants could reach a live study team member if they had any questions or concerns about the study.

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3.1.2 Non-African-American Black Women Focus Group Summary

The non-African-American black women's group was held in December 2003 in New York, New York. Eleven women were recruited; five women attended the session. Four of the women were from the West Indies and one was from Guyana. Two participants were between the ages of 18 and 25 and three participants were between the ages of 26 and 35. The reported annual incomes of the group members were quite varied ranging from less than \$10,000 to more than \$100,000. All were mothers of small children. Four of the women had children between the ages of 0 and 2, one woman had a child between the ages of 3 and 5 and three of the women had children between the ages of 6 and 11.

Part 1: How Do We Get You Interested?

Participants suggested several places that would be useful to receive information about the NCS. Suggestions included flyers, advertisements in daily newspapers, telephone calls, television advertisements, doctor's offices, "*American Baby*" magazine, WIC office, Health centers, letters or envelope inserts from insurance companies, posters in public places, such as public transportation, public service announcements, Babies R Us and Toys R Us website where a pregnant woman can register. "Anyplace where women buy baby products or stuff they need for the baby because the woman would have the information in front of them because they have to go to these places."

When asked about the type of magazines that would be most useful to receive information about the NCS, one woman said that it would depend on the target audience. At which point the women suggested teen magazines, high school guidance counselors, and the parent liaison in high schools as ways to target pregnant teens.

There were mixed feelings about the usefulness of mailings, letters or e-mails. One woman indicated, "I'm curious so I would read." However, others said that if they did not recognize the sender of the letter or email they would consider it junk mail or suspect the email could have a virus and discard.

The group expressed more support for letter mailings when the moderator suggested there might be a recognizable logo associated with the NCS. Woman who seemed to support receiving a mailing provided, "If you get mail and you've never seen the name before you read it because you want to find out what's in it." Another woman offered, "Young pregnant women want information and would be interested if you see something about pregnancy." "When you're pregnant you get a lot of junk mail. The junk mail you get, you know it because it says, 'The Family of So and So'. I never used to open it until I became pregnant and began looking for coupons. Once you become a mother you pay more attention." In response to the support and comments about looking for coupons another woman offered, "The majority of women having babies are 15 to 25 and not as frugal as you are."

Two other women offered, "It depends on who you're targeting. If it's younger, they don't open mail, they need something more than a catchy logo" and "young women don't pay attention to mail." Another woman responded with just the opposite, "my mother's not as inquisitive, I'm more inquisitive."

The group agreed that Oprah Winfrey would be an appropriate spokesperson. Additional recommendations for spokespersons included representatives from churches, pastors and Joyce Meyers. One woman provided, “someone like me who could break it down in layman’s terms that I can relate to. Not a politician or a medical person with too much medical background.” When asked about an appropriate spokesperson from the West Indian community, the women did not recommend anyone but rather suggested placing advertisements in West Indian stores and newspapers. Though one woman offered that the spokesperson should be “someone we can identify with from our own culture and background,” no names were given.

Before agreeing to participate, participants would want to know the purpose of the study, who the sponsor is, what are the expectations for participation (“all salient details”), and the benefits.

- “How would I benefit from the study, beyond altruism?”
- “How will my kids benefit if something good comes from the study?”

The group thought that the most important things to get out of their participation in the study were to benefit their own children and to receive information that they can pass on to their extended family members, and the safety of the program.

Part 2: What About the Time Commitment and Data Collection Activities?

One woman shared, “At a young age a child would probably participate, but at a certain age a child would probably not want to participate. As a teenager they don’t want to be bothered, they won’t want to participate.”

When the moderator prompted about the mother’s role (in maintaining the engagement) and commitment in participating, the woman replied:

- “I don’t think I would stop, but I think it would be a little difficult for the child to keep up and want to do it for so long. Even if it was just one visit a year, they probably would be like, ‘I don’t want to do this anymore’. I think it would be interesting to do, but I think it would take a little bit of effort to try to motivate the child to participate in the study.”

When asked at what age motivating the child to continue participating might be difficult, the woman thought it would be between the ages of 11 and 15.

Another woman suggested that it would be easier if the medical appointments for the study were included as part of the child’s regular annual doctor visits.

- “Since they have to go to the doctor every year for a physical exam anyway, I think it would just be easier to get the information from the regular doctor.”

Another woman shared,

- “When you have your kids you let them do what they have to do. So what if they don’t like it, but sometimes they have to do what they have to do.”

Another woman agreed that children should do what they are told is right even if they do not always want to. Adding,

- “I’m from the West Indies and you have to do what’s right.” “That’s a mind game the children play, they say, ‘I don’t want to go the next visit’ and you say, ‘Well you’re going to come’.”

The moderator asked the group to expand on their comments about these cultural issues regarding parents from the West Indies and several heads nodded and responded affirmatively:

- “We have a relationship with our kids, you have to train a child, mold them, shape them, bring them up to the way that you know is right. Not because the Americans say something. I love America, but not because the American system and other people do things that my child can’t; my child listens to me to do what’s right. This is about health and I’m a health freak. So I’m interested in your health and I want to know what is best for you and that everything is all right. So you will listen to what is right, it’s not who is right, it’s what is right. We don’t listen to what other people do, we do what is right so we sit down, we discuss it, and we analyze it. We started something, we’ve been doing it, and we are going to continue going until the time reaches to stop. It is important, it is intrinsic, it is educating your child so you have to tell them, let them know.”

Another woman offered,

- “We live in a world with different types of people. When you teach them they will recognize the difference between what they see at school, what they see at church and what they see at home.” Several women voiced agreement and said, “of course.” “West Indies people are different from Americans. American parents are flexible, West Indies, no, they are not flexible. They do what they have to do, there is no flexibility.”

Following the discussion of the number of office visits, two women shared that they were uneasy about providing blood samples at every visit. “That’s what I don’t agree with” and “Sounds like a bit much.” Another woman raised the issue of not receiving enough information about the tests that are conducted. She noted that giving the blood is not an issue, the issue is that no one tells them what is happening. The following discussions focused greatly on the amount and type of information required before they would agree to the testing. There were also concerns about whether they would be going to their own doctor or to specific study doctor. The group agreed that all of the tasks seemed possible but they would need to know in advance so that they could plan ahead.

- “I don’t see a problem. People think that they drain all this blood and they’re tired, but it restores. A lot of time they don’t go into explanation to these things because they think that will take too much time and the work is much faster so they won’t go into it unless you ask. Doctors think that people without their knowledge are laymen... Ask questions, have someone there to answer questions.”

The moderator asked the women if a flyer would be a useful tool to communicate/inform participants about project expectations and requirements (i.e., tests and samples taken). Two women agree and one shared, “These are things [tests] people have been doing for years and they never get answers. People need to know why.” There is consensus that written materials should be used to inform and educate participants about tests performed.

Another woman offered, “That’s why I asked if the doctor visit would be to a specific doctor or your [primary care]doctor because I think, like she said, if you know what you’re getting involved in with the blood and the urine every month or year or every doctor’s visit. If you know specifically you’re likely to be more receptive.” Another woman said, “For me the blood would be a problem, I’m extremely difficult to get blood from. I would not look forward to that at all.” The group asked how much blood would be required and whether it would be a “whole vial.”

The group agreed to allow the collection of the placenta “for health reasons.” The group also agreed to provide a breast milk sample “once it starts to flow.” The women would also allow the nurse or doctor to collect urine and blood from the child, but they would want to know how much blood would be collected.

One woman said that she would never provide hair sample from her child. Another woman reported that she would have a problem providing a hair sample before the child speaks. She stated that she has “an issue with the hair.” Another women suggested that it could be taken from a brush, but the one woman was adamant: “I don’t cut the boys hair until a certain point and the girl’s hair I’m definitely not cutting...The scissors aren’t going nowhere near the head. I have a problem with that one... I’m superstitious, you cut a boys hair before a certain age, you cut his tongue.” Another woman explained, “It’s a West Indies thing. You don’t cut the hair until after they talk.” The other women would agree to provide a sample of hair from the brush at any time.

The group agreed to the collection of buccal cells.

- “It’s not a problem, it’s not painful”
- “As long as the instrument is clean.”

The collection of baby teeth was only an issue for one woman in the group.

- “I have a problem with that. I saved all my kid’s baby teeth; I’m not going to part with them.” The other four women would have no problem providing baby teeth.
- “Back home when you lose teeth, when the teeth come out we throw them up on the roof and we say, ‘Racka [sic] bring new teeth and take old teeth.’”

The group agreed to genetic testing and said that they would want the results. There were some confidentiality concerns but the group noted that the consent form would spell out that they would receive the test results and that their confidentiality would be assured.

All participants agreed that children should not be allowed to consent for themselves until age 18.

Part 3: How Do We Keep You Interested?

At the outset of the incentive discussion, one woman asked, "Why do you think it is necessary to give gifts to have people participate? Although there are those who would not do something unless they got a gift...but there are some who say it is the right thing to do...because it is in their hearts." There was some discussion of altruistic reasons for participation but one woman pointed out that in a study as large as the NCS perhaps only fifty percent of the participants would agree to participate for altruistic reasons and that to gain the cooperation of the others would require incentives.

The group agreed that receiving information about their and their child's health is the most important. Several women agree that the electronic incentives (cable, TV, Internet access) are too much and too expensive. Those items they said were more feasible included coupons, gift certificates, school supplies, child photos. One woman felt that the donation to a charity would not be popular.

Another woman said that she agreed that the Cable TV was "a bit much," but she also believed that as children get older they will need more of an incentive than just the health reports. She added that at eighteen, a young adult is not thinking about health. Therefore, the smaller electronics such as the cell phone, beeper, and palm pilot would be appropriate for those who are age eighteen to twenty-one.

The group did not seem to understand the questions about receiving gifts in exchange for the biologic sample collection. Even after clarification, the participants seemed to be uncertain as to what they were being asked in this question. When asked what the group thought would be appropriate when giving biologic samples, responses included: \$25 gift certificate, American Express gift certificate, and coupons.

All of the women wanted to receive information as "often as they have new information." They would like regular updates from a representative from the study during business hours. They do not want to have to retrieve information from an automated voice system. The group would like to receive a newsletter with updates about the study. One woman offered, "If you participate in study, you're going to read about the study."

Part 4: Barriers to Participation

This group thought that the largest barrier to participation would be convincing the elders and other family members to participate. One woman expressed concern that when she took all of the information home and reviewed it, that she might not feel the same way about participating.

- "This is the first time I'm addressing this situation, I don't know if tomorrow or next day I'm going to feel the same way. It's not that I'm going to change, it's like what you said before, and it would involve my whole family. With all this information, I try to sit down and talk about it. It's not that I know how they would react because everybody has their own mind."

Another woman said that older family members are often more mistrustful and would question the confidentiality of the study and the reasons for providing personal health information. Also, because they are set in their ways, they would be difficult to persuade.

- “Because it’s the entire family that’s participating, they might not all feel the same way [as I do].”

When the moderator asked how these women would handle a situation in which an older family member did not recommend participating, the woman said that she would reconsider participating and added that “it would give me second thoughts.” However, the woman indicated that she would likely ask the NCS for clarification of questions and concerns and more information about the study. This woman would want to “keep both lines [of communication] open” (between NCS staff and her family members who were not comfortable participating).

During this discussion, one woman asked how the study would keep track of families that move, both in and out of the country, such as military families. She is part of a military family that has lived outside of the country for six years and she was concerned that military families might be left out of the study.

None of the women had any experience participating in research studies and none reported any negative feelings regarding research studies.

3.1.3 Asian (Chinese-Vietnamese) Focus Group Summary

This group was comprised of women from Chinese and Vietnamese descent. The focus group was held in Los Angeles in December 2003. Thirteen women were recruited and eight attended. Four of the women were Chinese and four were Vietnamese. Two women were age 26-35, two women were 36-40, and four were 41 or older. Total annual household income ranged from \$10,001 to more than \$100,000. Three were high school graduates, two had some college, and three were college graduates. The group was evenly split between pregnant women and mothers (four each). All eight women had young children. Six had 1-2 children and 2 had 3-4 children. One had children under 3 years old, four had children aged 3-5, and five had children aged 6-11.

Part 1: How Do We Get You Interested?

The best places to hear or read about the NCS are doctors' offices, clinics, or hospitals and schools. They liked the idea of having brochures about the study sent home from school with the quarterly student reports. This group also believed that places and events specific to the Asian community would be especially good for contacting Asian women. They mentioned community organizations, Asian festivals, the Chinese service center, and Asian Pacific clinics. Other places they mentioned included child care centers, places like the welfare department and the work source center, entertainment places, parks, and recreation centers, and religious buildings.

The women also liked the idea of hearing about the study on television, radio, or web sites, and even through signs on buses, but did not like the idea of getting a letter or a phone call. They noted that if they received a letter, they would throw it away. The women did not like receiving calls because they wanted public dissemination of the information. One person mentioned having study representatives come up to people in parks and another mentioned handing out brochures at community service centers.

- "TV is the strongest...Chinese channels."
- "Radio stations for Asians."
- "Asian web sites."

The women also believed that word of mouth would be effective and saw themselves (as focus group participants) as emissaries to the community leaders, who would then endorse the study.

- "Words of mouth...They can recruit their own relatives and friends. They can recruit them stronger...We can explain to community leaders and they can explain to the community."

The women agreed that they would want a lot of information before making contact with the study staff. They would want to know the benefits, the length of the study, what they have to do, its purpose, how the results would be used, the location, the cost, and whether they would go to their own doctors. They were especially concerned with the logistics of where the testing would be done and transportation issues.

- “What benefits them most...Why would I want to do this? What’s good for me?”
- “How long do I have to stay in this research?”
- “What do I have to do?”
- “Where is it going to be held, the location of the tests?”
- “Transportation...How will I get there?”
- “What is the cost? Do I have to pay for it?”
- “Would this disturb my daily activities, my lifestyle?”
- “Who will perform the services? Are we going to our own doctors?”

What would interest this group most in participating in the study are the health benefits for the children and family.

- “For better health for your children...the future of your children...a safe environment.”
- “To protect the next generation from many diseases.”

To participate in the study the women asked for free transportation (someone to pick them up and drop them off) and free child care. They would also like free college education for the child or a scholarship. One person mentioned that what would interest her is a “drawing for prizes.” Because participating would be an honor, a couple of participants would want an acknowledgement.

- “At the end of the study you get a certificate or award.”

The group also indicated that the best way to interest them was either through word of mouth or the endorsement of a community leader or a teacher.

- “I wouldn’t trust what you have down on paper. [It is] better a relative tells you. The word just spread...more convincing.”
- “The community leader is best, then second is the medical experts.”
- “If the teacher...tell the parent, the parent would trust the teacher more.”

The most important things that the women would want to come out of their participation are test results and benefits. They were interested in the benefit to their own children, but also to the overall public health of all people, not just for themselves or for Asians. The group wanted immediate feedback so that they could take measures to prevent illness. The women assumed that their children would get more health care by participating than they would otherwise. One person said the most important thing would be free education, a scholarship, or educational credit for participation in the study.

- “The next 20 years my children will go healthy...I expect my children will have more vaccines, more programs.”
- “Environmental cleanup...a much safer environment for my children.”

Part 2: What About the Time Commitment and Data Collection Activities?

In response to the question of whether they thought they could maintain their level of participation throughout the study, the participants responded that they did not find the level of participation of activities to be burdensome. They did not think there were too many doctor's visits, but they wanted to piggyback the study doctor visits on the regular visits with their own family doctor. They were concerned with logistical issues such as location, transportation, and child care and wanted to know again if they would have to pay for the visits. They expressed concern that it would be hard to keep a child in the study after he turned 18 and that mothers would forget about the appointments unless the study sent them reminder notices. Participants asked more questions about what the doctor visits were for and what they would do to their child.

- "Your family doctor... You have to go for vaccinations... for the doctor's office visit it is nothing for a child being healthy."
- "It's not too many doctors' visits."
- "If I committed to it, I would do it."
- "Not go too far from my house."

Group participants had no problem with the collection of the environmental samples, completion of the survey, or with the collection of most of the biological samples. They would want the results of all the tests and would want to know how the results would be used. Collection of water and dust were not a problem. They would be willing to complete a questionnaire one or two times a year, but three times a year would be too much. They would give up the placenta but would want to know if they found anything wrong. Likewise, they had no problem with agreeing to provide the meconium, hair and fingernail clippings, and buccal cells. They would also allow collection of infant blood and urine, but they noted that it is hard to get an infant urine sample. All group members were willing to provide baby teeth. Although, one group member said she usually keeps the teeth, she would agree to give them up if required by the study. The group was willing to provide breast milk and would like the study to provide a breast pump. Group members were divided on whether they would prefer to send in a breast milk sample or have someone come to the house to pick up the sample, and agreed that it was best to have a choice on this issue.

- "Make sure the water you drink is clean."
- "I keep the baby teeth, but it is ok if I have to participate for the research."
- "Send it [breast milk] in or someone come over to collect it... either way."
- "It is hard to get [an infant] urine sample."

The type of biological sample they were most concerned with was blood. They explained that Asians do not like drawing the blood. The Asian moderator summed up their comments by saying that blood is precious, the source of life. Blood is hard to generate. If you lose blood, your health will be damaged. Then many Asians believe you have to eat one or two bowls of rice to replenish the blood. They said also that Asian women have small veins, so that drawing blood is painful. Only one person

said that giving a tube of blood was no problem. They wanted to go to their own doctors to give the blood sample and use the results from the regular doctor's visits for the study.

- "Drawing the blood is too much."
- "Asians don't like drawing the blood... You eat a bowl of rice and you get your blood back."
- "My veins are little. It is hard to draw blood... It is very painful."

Genetic testing was acceptable to these women. The key was getting the results of the testing and being ensured of the confidentiality of the results. The results should be given quickly so that they can make use of them. They would not participate if they did not get the results and thought that in that case the researchers would be hiding something from them.

- "Fine, if you can find out the problem, you can prevent things for the child."
- "Confidentiality?... keep it in the family."
- [If they did not get the results] "it would make me worried. Is there something wrong with me?"

Finally, all of the group participants agreed that 18 is the age at which the child should sign the consent form. "Before that age, mom decides."

Part 3: How Do We Keep You Interested?

Group participants liked the idea of receiving gifts for their participation. Gift ideas that they liked were infant supplies and diapers, gift certificates, and coupons. For teenagers electronic equipment and palm pilots would be good gifts. They did not want the teenagers to get access to the Web though. What they all agreed is that the gifts should be appropriate to the child's age and stage of life and should change over time. One person suggested that gifts be given twice a year. Because donations to charity are socially desirable, they were reluctant to say that they don't like to donate. Instead they asked for the choice of whether they get a gift or make a donation.

- "Follow the stages... When you are pregnant, gifts of infant supplies and diapers... How old is the child? Stages... gifts different for different ages.. Every 2 years review the reward. Especially by the time of teenagers. It is tough to keep them in line. Reward them with electronic equipment, palm pilot."
- "As the study goes along, different kinds of rewards?"

One woman said that if she had one child in the study, she would want the next child to join the study too. She asked how much the gift would be if two children participated and thought there should be a bonus in this case. Another woman suggested that the study hold "parties for all the study participants." The entire group liked this idea but narrowed it down to parties for all participants in a state. They wanted to be able to socialize and network with other participants.

Asked whether they should be offered a gift each time they provided a biological sample, they said they liked the idea of giving the child a gift with a card attached that acknowledges their participation. They also suggested that the child be awarded a certificate he could feel proud of.

- “When younger give toys, a little older clothing, and older a gift certificate...Acknowledge participation card with the gift.”
- “A certificate for the child...He can show his friends...feel proud of it.”

Group participants also liked the idea of receiving money for their participation. They especially liked the idea of receiving money for school tuition. The Asian women were initially reluctant to mention particular amounts of money. After one woman suggested \$100 a month, everyone else said that was too much. Someone else suggested \$500 for the whole year and another responded that she did “not think the government could afford to pay that much.” In the end they settled for an amount between \$200 and \$500 a year.

- “I don't think we mind if they give money.”
- “A reward for school tuition.”

Most said that they did not think gifts would make them feel like they had to participate. One person said that “other people” might feel that the gifts were bribery. People in the group countered this by saying that participation was voluntary and the gifts were given only as a token. One person said her child may feel she is “selling” him. In response to this, another person said that the parents need to explain to the children that this is for public health overall.

- “In a way, with all those gifts being received it is kind of like a bribery to keep you going.”
- “As my child gets older, my child says ‘Mom, you are selling me!’”

The women would like to be kept informed of what is going on with the study. They wanted to know “all the activities.” They especially liked the idea of receiving newsletters every month or a study website that says what is new and what is updated. However, they want to be assured that their names would be kept confidential. Other acceptable media to keep them informed include e-mail, mail, and TV announcements. They did not want to receive phone calls.

How frequently the women want to receive information is determined by the type of information. They want to receive personal test results right away so that they can take action if necessary. However, the women wanted to receive information about the study every 3-6 months or at anytime via a website. The kind of information that they are looking for includes the progress of the study, study results, any changes to the project, and lifestyle and prevention information.

- “Some tests you need to find out the results as soon as possible.”
- “Get information to do something about it.”
- “Results...How many percent that had this problem and how many percent had that problem and what caused them.”

- “Not just percents...but also how we can prevent all that.”

Part 4: Barriers to Participation

The women raised several issues that related to whether or not they would participate in the study. These issues were the long time commitment, number of visits, convenience (location, transportation, logistics), and a doctor who can speak the same language.

- “To me it is more like the commitment...It is a long commitment.”
- “Use the same results as with the family doctor...No extra visits.”
- “The doctor speak the same language...more comfortable with the same ethnic background.”

When the women were asked about any specific concerns they had about participating, they mentioned a number of trust and risk issues. The group wanted to be sure that results were kept strictly confidential. They said that the government and researchers should sign a pledge not to release the information under any circumstances. Some were also concerned that the researchers might not do the testing the way they are supposed to or that they might not do the right thing. They would want a second opinion. As for issues relating to risk, they did not want the study to put anything into their (biological) systems, like giving them shots that might have side effects. They were not concerned that the US government is sponsoring the study.

- “I don’t know if they really keep my family history confidential.”
- “You [the researchers] have to sign the consent [confidentiality pledge].”
- “Nobody can get my information, not even the courts.”
- “How do we know they are doing the right thing? We might want a second opinion on the researcher’s result.”
- “How do we know that they really do the research or testing like the way they are supposed to do?”
- “Just collect samples, not put anything into your system.”

To address their concerns the study sponsors must guarantee their confidentiality, show that the researchers are qualified and credible, show that there will be no risks to their health from the testing, and give them information for follow up and referrals for second opinions. They were interested in seeing results from past research to show the importance of the study and its scientific foundations. The medical experts and researchers have to have credentials because credentials are important to the Asian community.

- “First they must show they come from a real respected group, and they qualify with the program and show us the direction they will go that will earn our trust.”
- “Show us some strong result in the past to show us they go in the right direction.”

When asked if there are any specifically Asian issues about participating in the study, the group members brought up giving blood and taking medications.

- “Asians don’t like withdrawing blood. They can’t afford to give blood. They are going to faint. [They must] eat a bowl of rice.”
- “Asians hate taking medications...Asians don’t understand that medicine balances their body.”

Group participants were concerned about what the study would do if they found a medical problem. While one woman said that she would want to be treated by the study, most wanted the testing information, recommendations for follow-up, and referrals to go get a second opinion.

- “Just inform me. It is up to me to find a doctor.”
- “Referrals...get a second opinion.”

They were also concerned about what would happen if they moved to another state or out of the country. “All the paperwork with my family doctor will have to be done again...a hassle on me.” They would also need a way to contact the study to update an address or ask questions.

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3.1.4 Asian (Filipino, South Asian Indian, or Indonesian) Focus Group Summary

This group was comprised of women who self-identified as Filipino and South Asian Indian. The group was conducted in December of 2003 in New York, New York. Eleven women were recruited and seven women attended the session. The group was quite varied with respect to age. There was less variation with respect to annual incomes across the group with five participants reporting an annual income of between \$10,001 and \$30,000 and two participants reporting an annual income between \$30,000 and \$50,000. Two participants had completed high school, two participants completed some college and three participants completed some graduate education. Three of the participants were currently pregnant and four were parents of young children. Six of the participants had children ages 6 - 11.

This group was fairly reserved and not very willing to share their thoughts and ideas. The moderator tried many approaches to drawing the participants out including using prompts and pointed questions, with the exception of one woman, participants were difficult to engage in conversation. One woman spoke only when the moderator addressed a question to her directly and only nodded in response to a few questions and statements from the group.

Part 1: How Do We Get You Interested?

Participants suggested several places that would be useful to receive information about the NCS. Suggestions included posters and brochures in a doctor's (OB-GYN) office, maternity wards, flyers or posting in the local post office, magazine advertisements, shopping mall, maternity stores, on the Internet or on television.

The moderator asked the group about receiving information on the NCS via email. While one woman said that she would be interested in receiving an email another stated, "I would consider it as a junk mail."

- "I would participate because I always go online, I'm always online"

When prompted by the moderator on their sources for information, one woman mentioned friends. There was no response when the moderator asked the group about community centers, but one woman offered parties as a source for information and another woman suggested schools and universities. The group did not think that being notified by telephone would be a good idea.

The women did not differ greatly from other groups in what they wanted to know before they would make contact with the study staff. Responses included:

- "Benefits, what am I going to get from it"
- "How does it impact the health of children"
- "What are the risk factors"
- "How long is the study going to be"
- "What kind of medical tests"

The moderator asked whether the woman would want to know how frequent there would be tests. One woman added that she would want to know “why they have to do that (test)” and “why focus on children only.” There was no response from the group when the moderator asked whether there was any interest in the Asian community knowing the sponsor of the study and whether it is important that the EPA or a federal agency were involved.

When asked what would most interest participants and their families in participating in the NCS, one woman stated “what will my kid get from it, you said 20 years. Will he have benefits, like insurance things... benefits of kids?”

The moderator asked the group about their interest in being part of a national study. One woman responded, “I think it would be a good feeling, you could be a part of the success of a study.” Another asked “what kind of medical tests?” another stated “to learn more about children’s health with regards to environmental hazards” and another responded, “pollutions, neighborhood, vitamins...”

Three women agreed when asked if it would be beneficial to have a famous spokeswoman for the NCS, but no one provided suggestions on an appropriate spokesperson.

The group did not respond to the question asking what would be the most important thing they would hope to get from participation. The moderator suggested issues such as the health of the children, benefit to the Asian community, and the contribution to science as important things to see come from participation in the NCS. One woman responded “like what you said, the thing for the health of the children.” The majority of the other women agreed.

Part 2: What About the Time Commitment and Data Collection Activities?

When asked their thoughts about the time commitment and level of activity, one woman responded that she would have no trouble maintaining the required level of participation. One stated, “It’s an average, it’s not that frequent... it’s like two doctor’s visits. You’re not going to be that bothered.”

When asked about home visits by NCS representatives, one woman responded, “I think that I would not be bothered by just one visit.”

When asked whether they would be bothered by doctor visits after the birth, one woman responded, “No, I think it’s the study.”

The moderator asked the group if they thought it would be difficult for people to take children to the doctor that often. One woman nodded her head and another responded that the “first two years not hard, still babies... teens, when you’re older and you’re going with your mom, but you’re part of the study. You have to tell your kid you’re part of the study. But you said it’s every other year so it’s not that bad.”

The moderator asked about including the NCS doctor visits with the child's regular doctor visits and one woman responded that "it would be easier; you don't have to explain to kid we're going to doctor because you have to get shots and the survey will be there too." Another stated, "no for me, it's not, it's for the kids, because it's for the kids health, get examine, it's ok." Another woman provided that "it's ok."

When asked whether they would be comfortable with having someone come to their home, a woman responded that, "risk you take when you sign for the study. They have to have the home visit so you have no choice." Four other women nodded their heads in agreement.

When asked about whether they had a preference for the NCS providing a home kit versus a home visit for collecting tap water or house dust, four women felt that it would be easier for someone to come to their home.

The women did not seem to think that the survey would be problematic. Responses included, "not bad" and "it's only 20-minutes, not much." Four women preferred to receive a mail survey, one woman preferred an Internet survey, and two women preferred a telephone survey.

When asked about collecting blood and urine during pregnancy, the women were somewhat confused but suggested that more information be provided to justify the tests. A woman asked, "Would it have to be blood or urine? Do you have a choice, blood or urine?" Upon prompting from the moderator, the group agreed that giving a sample of urine would be easiest. The women did not express concern when asked if they would have a problem with providing a sample of blood.

The women all agreed that they would be willing to allow testing of their placenta. No other responses or comments were provided. The majority of the women would also allow the collection of the cord blood. One woman asked,

- "Why do you need to test the blood? It's like taking the amniocentesis?"

Most of the women offered that they are not bothered by providing a sample of their breast milk. One woman replied, "It's ok because it's for the test." The women did not feel that providing a sample of breast milk would be an issue for the Asian community. Comments included, "if you have milk to give,"... "maybe it's hard for her to give milk."

The women agreed to the collection of the meconium sample.

When asked about collecting blood and urine from the children, one woman asked if providing blood samples was "really necessary" and another offered that she would not have a problem with blood samples from a baby provided the baby was healthy and the pediatrician approved.

When asked if they would be willing to provide hair samples, the women had questions about how much hair would be required and agreed that if it was just a few hairs it might be okay. When asked

how they felt about providing fingernail clippings, one woman asked “Isn’t it going to be gross?” Another woman provided that it would be easiest to collect the sample themselves and send them in.

One participant shared that she would prefer the nurse as opposed to a technician collect buccal cells. Another asked, “is it necessary for collecting these samples for this environmental study?”

The participants agreed that there are no cultural issues with providing child’s baby teeth for testing.

The women did not have any issues with respect to genetic testing but several participants agreed that they would want to know the results of the tests. One woman commented that it would be beneficial to know whether something was wrong or would be wrong later in life.

When asked whether confidentiality was a concern, one woman said it was and others provided no response. However, when asked whether privacy were an issue or concern, one woman replied, “I think so” and another offered, “Privacy is very important to us.”

One woman stated that she did not understand the issues of confidentiality and privacy. The participants felt that since the information would be shared and analyzed that it was not confidential and private. The moderator explained that results would be analyzed in the aggregate with no information to identify individual participants.

When asked at what age do you think it would be appropriate for your child to sign the consent form for him/herself, three women said 18 years of age; two women said 19 years, and one said 21 years was an appropriate age for a child to sign a consent form him/herself. Another woman felt that it depended on the individual child’s ability to understand consent.

Part 3: How Do We Keep You Interested?

When asked about incentives, a consensus of women agreed that an educational grant or scholarship would be an appropriate incentive to stay in the study. A few laughed at the suggestion of coupons, while one woman said coupons would be okay for the first years. Another woman offered gift certificates at children’s stores and school supplies as appropriate incentives. One woman mentioned that the child’s photo would also be a nice gift. Two to three women indicated that they thought cable television, Internet access and web TV were unnecessary expenses that were not really important.

The women did not respond when asked if they thought the same gifts would be appropriate in return for the biologic samples.

Similarly when asked if they thought a monetary incentive would be appropriate, only one woman said, “That would be nice.”

When asked if any of the items discussed would make them feel coerced into participation or as if they had no choice, one woman shared that she thought the cell, beeper and electronic items may make participants feel this way. Another woman said,

- “It’s not necessary, this study is for a good cause so the money is not necessary.”

Most of the participants agreed that they would like to receive information about the study. Though a majority said that they were not interested in a newsletter as a source of information, two women would like to stay informed by receiving information through the mail. A consensus agreed that the telephone was not a good source for providing study participants with information. The women offered a variety of intervals for receiving information- two months, three months, six months, quarterly, and yearly. Most of the women agreed that they would want to receive summaries and findings of the study.

- “We want to know their results.”
- When asked whether they would want information on inconclusive results, one woman asked,
- “What’s the use in knowing if it’s not going to be interpreted?”

Part 4: Barriers to Participation

The women indicated that the only thing that would prevent them from participation is “if there is a great risk of participating.”

When asked specifically about how they felt about government involvement, two women indicated that they had no opinion regarding government involvement in the study. Several women agreed that they trusted the researchers to protect their confidentiality and that they had no concerns regarding government involvement. None of the other participants provided a response. The women did agree that that knowledge regarding their doctor’s participation would encourage their participation.

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3.1.5 Hispanic (non-Mexican-American) Focus Group Summary

The non-Mexican-American Hispanic group was held in New York City in December 2003. Eleven participants were recruited, and six attended. All participants were between 26 and 35. Three were from Puerto Rico and three were from South America (Columbia and Ecuador). The group was quite varied with respect to income with three participants reporting income between \$10,000 and \$30,000; one participant reporting between \$30,001 and \$50,000; and two participants reporting between \$50,001 and \$75,000. One participant had completed high school, four women completed some college and one was a college graduate. All were living in urban areas.

Part 1: How Do We Get You Interested?

Overall, the group agreed that they would respond best to sources of information from institutions such as health clinics, hospitals, doctor's office, WIC offices, welfare centers, social security offices and places people take children like zoos, museums and schools. The response was mixed as to the effectiveness of magazine and television advertisements. The group acknowledged that many people do not access the Internet, but it may be an option for a small number of participants. Several of the women noted that they would not open email from someone they did not know. The participants agreed that if any information was mailed, it should be in an "eye-catching" envelope. Otherwise they would just throw it away. Phone calls were viewed as a possibility. The group was curious how the study would get their addresses and telephone numbers though.

The group's biggest concern was how to gather more information about the purpose and benefits of the study. The group wanted to know what benefits there would be for their own child and to children in general. The group would like to know during the recruiting or enrollment process who is conducting the study, the purpose of the study, how the data will be used, how much time will be needed, where they will have to go and what will be expected of them. The group agreed that they want to receive all of the information "up front" before they sign anything and they want a steady study contact.

One member of the group misconstrued the study as a social service program that would follow the child and arrange services such as schooling, housing, medical care, and "pantry food." She noted that in these programs there is a social worker that works with the family very closely and observes the child's growth against a set of standards. She said that there are already programs like the NCS and that she was in one that followed her child from birth through age four because the child was born prematurely. She commented further that these programs are for single mothers who "have nothing." She found the workers very intrusive. Based on this information, the group asked what would happen if the environmental tests are negative. "If they think my child is not developing according to their standards – are they going to take my child away?"

The group was very interested in what would happen with the results: "What are you going to do with the results?" They want to know what impact the study will have on the environment and the child, and what the goals of the project will be. One woman wanted to know if the project was going to provide

good schooling and housing so that they will make progress. The group agreed that participating in a large study would be a good idea.

The group agreed that celebrities and community leaders were not viewed as positive spokespersons because the public does not trust them because “they get paid to do it.” It will be better to have a regular “mom” as a spokesperson; somebody with whom they can identify.

Part 2: What About the Time Commitment and Data Collection Activities?

When the group was presented with the proposed activities, the first question was about transportation. One woman noted that all government programs provide transportation. The women thought the plan was “lenient.” The one woman, who thought the NCS was another social service program, noted that the plan was not nearly as intrusive as the program she had participated in before. The group felt that the frequency of visits was appropriate during the younger years. However, they recommended the visits be at the same time they take the children to regular appointments rather to plan them separately. One woman noted that it all sounded too personal.

The group agreed that a research team member visiting their home to collect tap water or house dust would be acceptable “as long as it is a scheduled visit...” They would agree to a home visit once or twice a year. They did express a preference of not collecting the sample themselves even if the study uses a kit with prepaid postage. One group member noted that right now she has something at home that she was to return and it has been sitting for a while. The group preferred to have someone else come to do it because they are usually too busy and would forget about it. There were some concerns about the collections and results, “What are they going to do if they find problems in the water and dust – are they going to move me?”

The group was mixed regarding the purpose and the mode of the surveys. First they were confused about the content and whether the survey was for another study or the NCS. One woman said that she would do it if she were paid an incentive or given a gift certificate for “Toys R Us.” She stated that she would do anything for her kids if they could get a gift, or some money or food. They suggested giving 3 options to the participants: phone, mail, and Internet. One woman noted that some women might not be able to see to complete a mail survey. Four participants would like to complete the survey by phone, and two would prefer the Internet. One participant suggested that during the enrollment process we should ask the mothers for their preference. One woman also suggested that it would be interesting to share ideas and opinions with the same group about your child development 2 or 3 times a year.

The issue of providing biologic specimens became quite confusing. They did not understand the relationship between the samples and the environment. One woman stated that she was becoming “scared” by the discussion. The women expressed concern that the study was asking too much of them. For the most part the group considered that providing urine and blood samples were acceptable during the prenatal visits because “they do it anyway at the clinic.” One participant said “no blood because that’s my DNA” One woman said that she would not agree to testing if she were pregnant. She did not want to put the baby at risk. “If I am pregnant I would be more skeptical to testing.”

The majority of the group said that they would not provide the placenta for tests. They thought it was an unusual request. One participant said “no, why they didn’t do this years ago? What is the difference now?” Another participant said: “yes, if it’s in writing and this is not about me, it’s in general taking sample from everybody to get results.” Another person said: “if I know that something is wrong with my child, I would give it [the placenta] to find out more information.” There was no consensus among the participants, and only two participants expressed an interest in helping to understand more about illnesses through a study like this.

The question about providing the breast milk sample raised some issues. One woman said that none of the tests were important and that if children grow up in bad neighborhoods, then they grow up bad. All of the women said that they would need to understand more about the study because the sample collection was so personal and they did not understand the relationship between what the study was trying to learn and the sample collection. The group finally agreed to provide the breast milk sample and to use a pump. However, they said that they wanted to provide the sample at the office or lab. There was consensus not to mail any of the samples because they might get lost in the mail. All agreed that the sample should be collected at the hospital and ideally during same appointments or visits.

The participants were extremely skeptical about allowing the physicians to examine the umbilical cord blood. One woman said she would provide the cord blood only if her child was sick. Another woman mentioned that cord blood could be saved and used if another sibling becomes sick. A participant replied that she would not want the cord blood back from the study because it would probably have been injected with many materials and substances--“I wouldn’t trust them at all.” The same woman said that this whole conversation seemed funny to her because it was so complicated. She noted that someone would have to sit down and explain this all to her because she found it so confusing.

A second area of concern was with the collection of meconium. In general, there was lack of understanding among participants of why the study would collect meconium. One participant said: “I remember when I was little and sick they collected a stool sample. It’s understandable why they would collect it.” Another woman added that her story made sense because she was sick but that the collection of the samples from healthy children does not make sense. Another woman said that although her pregnancy and delivery were normal, her son is now autistic and she would do almost anything to learn about what happened. She was involved in a clinical trial in which they wanted to try an experimental drug on her child. She did not agree because she was afraid of what could happen. She noted that they felt treated like “guinea pigs.”

There was some concern about doctors collecting samples of buccal cells, hair, and fingernails from the child. Confidentiality was the main concern. The group would want to know what type of data can be obtained from the samples. One mother said: “I would prefer to do it myself and give to the person.” Another participant said: “for me is just a study – it’s ok.” Yet another participant said: “if I am not getting anything out of this I would not participate.” They all agreed that asking for baby teeth was too much; they consider them memories and some mothers make charms and earrings with their baby’s first teeth.

Overall, the group had no concern about genetic testing as long as it is completely confidential. All members of the group would want to know the results. The group seemed to become concerned about why we even asked the question about receiving the results. They would not agree to participate if they didn't receive the results of everything. The whole group agreed that they may not understand the results; they would have to receive it "in plain English" or have the doctor to explain it to them.

The group was divided regarding the age that the child should sign his/her own consent form. One participant said at age 13, one participant said at age 16 and four participants said at age 18.

Part 3: How Do We Keep You Interested?

The group suggested receiving health insurance for the child or assistance with costs of medication for the child. The group did not like the idea of cable service or Internet since they view these incentives directed more towards the parents than to the child. Coupons and gift certificates, or food vouchers should be at least \$100.00 to buy something for the family. Some of the gifts mentioned were diapers, since they are very expensive and are used a lot. Nobody liked the idea of charitable donation.

One woman suggested there should be gifts for the mothers as well. Another woman mentioned that savings bonds, school tuition or scholarships would be a very appropriate incentive considering that the study is for 21 years.

The information about the child's health was not considered an option or a gift. It was considered a "given" and should be sent regularly to the families. The group also suggested having different types of incentives for different types of tests and participation, one participant said: "I think every time you come to visit me I need something for me and my child."

No one in the group felt that incentives would make them feel obligated. "I don't feel I have to, but something will help"

When asked how they would like to be kept informed about the study, the consensus was to offer three options to mothers since there are so many different lifestyles and preferences. These options would include: newsletter or mail, phone call and/or attending local meetings at reasonable times. All but one participant agreed to receive information every 6 months. The other participant said: "if it's new information, fill me in – no limit." The preferred frequency of contact was 6 months or a year.

The entire group wanted all of the results of the study. One participant said: "if the information cannot be tested or defined/interpreted I would not participate."

Part 4: Barriers to Participation

The participants said that if the information would not be released for any reason they would not participate. One participant said "no incentives, no participation." Other concerns were confidentiality, and the possibility that the samples were collected for one purpose and eventually they are used for some other kind of research. In order to participate, they must be convinced of the benefit to the child, and they

would require much detailed information to make this decision. All of the participants agreed that if their health care provider is involved they would feel more comfortable because they would have already an ongoing relationship with the doctor.

The group agreed that it wouldn't matter if other Hispanic families and doctors are part of the study as long as nationwide participation from "all levels" is included. They would want to know who is responsible for the study and who has access to the information.

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3.1.6 Mexican – American Focus Group Summary

The Mexican-American group was held in Los Angeles, California in December 2003. This group was conducted in Spanish. Eleven participants were recruited and nine participated. The women were from all age groups and most reported incomes between \$10,000 and \$30,000. Only two participants completed some college, six completed high school and one participant did not complete high school. The group was generally agreeable. The opinions of group members were very similar and there was very little “lively” discussion.

Part 1: How Do We Get You Interested?

Overall the group agreed that they would respond best to sources of information from institutions such as health clinics, hospitals, doctor’s office, WIC offices and schools. Information from these sources was viewed as more legitimate and more likely to catch their interest. The response of the group to finding the information about the NCS in magazines and on television was mixed. Some said that they never watch TV and others said that they never buy magazines. The group noted that billboards on buses could be vandalized and the information would not seem as important as if it came from their health care provider. The group also did not think that the internet would be a good mode of communication since many people do not have access to the Internet. Phone calls were also not viewed as a good method since the group noted that they receive too many calls and don’t always pay attention to what the calls are about.

A common thread throughout the evening was concern about being informed about the purpose and benefits of the study. The group wanted to know what benefits they would receive if they participated in the study.

- “Knowing who is doing the study, why it’s being done and how the data will be used is important.”
- “Knowing how much time will be invested, where I will have to go and what will be expected of me is also very important.”

The women said that knowing others who are participating in the study and knowing the purpose of the study would increase their interest in the study. Several of the participants would want to learn more about their child’s illness or disability.

The women were generally positive about a spokesperson if it was a medical expert such as the Surgeon General. Celebrities and community leaders were not viewed as positive spokespersons.

The women noted that the most positive outcomes of participating in the NCS would be the knowledge that that they were contributing to science, learning more about health in the Mexican-American community and improving children’s health.

Part 2: What About the Time Commitment and Data Collection Activities?

The women continued to stress the positive effects of the study to children’s health and to the health of women in general. The frequency of visits seemed appropriate during the younger years.

However, they recommended annual visits in the older years rather than visits every other year because they believe that it would be more difficult to remember if the activity was every other year.

- “Since it will be harder to get the children to go as they get older, it’s better to keep it on an annual basis.”

The group seemed surprised by the one hour length of the proposed doctor visits and noted that one hour with the doctor is so much more than the usual 10 minutes that they now have with the doctor. Some thought one hour would be good, others thought it would be too long. The group was also concerned about transportation.

- “Availability of transportation is important since some people do not have cars or don’t drive.”

The consensus in the group was that they wouldn’t mind someone coming to their home to take water or dust samples. However, they would want the technician to make an appointment in advance. Only one person in the group seemed slightly concerned about someone coming to the home. She felt she would need to clean and be ready for someone. There was no consensus regarding the frequency of the sample collection. The group was reluctant to perform the sample collection themselves because they might forget to collect the sample.

- “There is more risk of forgetting to do it even though it would be more convenient.”

The group did not agree on a preferred mode for completing the survey. Some thought it would be too long to do on the phone. However, some members of the group were concerned that if the survey was conducted by mail, they would not have the opportunity to ask questions about the survey content. The group finally agreed that having a mail survey with an option to complete it by telephone or a toll-free number to call with questions would be optimal. No one favored completing the survey over the Internet. The group agree that the survey should be easy to read.

- “Having the questionnaire in ‘everyday’ language is important.”

There was no resistance or concern about providing any of the biologic samples as long as the testing was thought to be necessary to achieve the goals of the study. One person noted that she had read that placenta is used to make creams and cosmetics. Only one person was concerned about knowing the results of the tests on biologic and environmental samples.

- “We don’t know what happens to the placenta anyway so it doesn’t matter.”
- “When they asked me about an amniocentesis, I said no. I have nine kids and I just trust in God that things will be fine. Sometimes those tests aren’t 100% correct.”

Overall, the group agreed that the biologic specimens should be collected during a visit to the doctor, hospital, or lab. Some of the women were concerned that the environment at home might not be

sterile and preferred that the biologic specimens be collected during office visits. Other women were willing to collect the specimen at home but had concerns about shipping the specimen to the lab. They would prefer to drop it off at the lab or doctor's office so that it would not get lost during shipping.

- "I would rather go the doctor's office and have someone take the sample rather than sending it in."

The only concern expressed about collecting samples from the infant or child was whether it would cause pain or discomfort to the child. The women would expect that blood would be collected by finger stick only and that large quantities of blood would not be drawn.

The women were willing to provide samples of hair and fingernails as long as they knew in advance what the samples would be tested for and received the results of the testing.

There was no concern or discussion about providing baby teeth.

The group had no concern about genetic testing as long as it is "100% confidential." All but one member of the group would want to know the results. One member was fearful of getting results. The whole group agreed that they may not understand the results and they would need clinical interpretation. If there is no explanation, then they don't want to know.

The group agreed that the child should sign his/her own consent form at age 18.

Part 3: How Do We Keep You Interested?

The group agreed that being kept informed of results and progress was what they wanted most from the study. This group was not interested in any specific "gifts." They were more interested in services being provided such as doctor's visits, children's medications and information on health.

- "Being informed about the process is more important than receiving gifts."
- "Receiving health insurance for the child would be very positive since many people don't have insurance."

One group member noted that no one in the focus group would have attended if it weren't for the \$50 incentive so obviously participants are interested in receiving something.

- "Most Latinos want something that is free."

One person liked the idea of cable service or food vouchers to buy something for the family. Only one person liked the Internet service. No one expressed a preference for the charitable donation.

There was consensus that gifts do help to gain participation even if it is not a valuable gift.

- "Some people are motivated by gifts."

There was mixed reaction to receiving money for participation. Some said that the Latino community can always use monetary assistance and others said that they don't need more beyond knowing that their participation benefits research and knowing that the child is healthy. No dollar amount was ever mentioned even after prompting. No one in the group felt that incentives would make them feel obligated.

- “If I'm interested I will do it, with or without the money.”

This group preferred to stay informed by mail and attending meetings or lectures every six months. The consensus was that a combination of methods would be best. The group was not in favor of telephone contact.

- “All of the results of the study would be important.”

Again, the group mentioned that they were not interested in participation if there was no explanation or interpretation of results.

Part 4: Barriers to Participation

Once again the group stressed the importance of being informed. The group would not be interested in participating if no information was provided. The group was also concerned about whether the study would take too much time or more time than is expected. The women also expressed concern that there wouldn't be any benefit from the study but they were not concerned about government involvement. The group wanted to be able to trust that the researchers will do what they promise.

- “Having the government sponsor the study has no impact. That just lets us know who is paying for it.”
- “If they say it's confidential, I trust it because it's the government.”

One way to reduce their concerns would be to have their own primary care physician involved in the study. The group had concerns about how much harm or inconvenience there would be to the child. For instance, “lot's of pricks for blood samples.” The group discussed a local incident where medical records were found in the trash of a medical facility.

The group was not concerned about nor would they be influenced by the race or ancestry of other participants or the researchers. It is, however, important that the researchers speak Spanish.

Receiving information throughout the study and being notified of staff changes is important. One participant asked if she would be able to withdraw. She asked if she would be signing a contract. They stressed information and maintaining contact information in case they moved.

- “What is most important is having all the information at the beginning of the study.”

3.1.7 American Indian Focus Group Summary (Southwest)

This focus group was conducted with American Indian women in Albuquerque, New Mexico in December 2003. Nine women attended the session. The women self-identified as members of a number of local tribes: 3 Navaho, 2 Acoma Pueblo, and one each Navaho/Lakota, Mescalero Apache, Nisqually, and Santa Domingo Pueblo. Three of the women live on a reservation and six of the women live in and around the Albuquerque area. Four women were pregnant and the others were mothers of young children. There were no college graduates. Two women had less than high school education, four women were high school graduates, and three women had some college. Eight of the women reported a total annual household income of between \$10,001 and \$30,000, and one woman had an income of \$10,000 or less. The women came from different kinds of areas: five women live in urban areas, one lives in a suburban area, and three women live in rural areas.

Part 1: How Do We Get You Interested?

The women said that the best places to hear about the study were doctor's offices, tribal groups, or community organizations. The community organizations that were mentioned included Head Start, WIC (Women, Infants, Children), the Indian Health Service, and a local Native American parent organization.

- "Tribal groups that deal with maternal health."
- "If you have an affiliation with an organization that is good...If you were familiar with the organization."
- "A parent organization they would trust."

The women did not want to receive a letter or a telephone call about the study. They indicated that they would throw away a letter and get too many calls as it is. They especially liked the idea of the doctor handing them a brochure. They said that the newspaper would be a good source of information and mentioned the Albuquerque Journal, tribal papers such as Indian Country Today, the Navaho Times, and tribal newsletters. The group was lukewarm on TV announcements and ads on public buses.

- "Indian Country Today and Navaho Times... That would capture their interest rather than the Journal."
- "Local newsletters from tribes."
- "Something like this [EPA NCS brochure]...I'd look at it because it has to do with children."

The woman said that they would like to have as much information as possible ("the who, what, where, when, why") before they would contact the study. The women would like to know what the study is about, the sponsor, who is eligible, what they would have to do, and where they would have to go to get screened. They also wanted to be assured that by calling they were not committing themselves to the study.

What would most interest them in participating in the study is awareness of how the environment affects their children and how the information from the study would help children. They also noted the

need for flexibility and options, such as being able to go to any hospital if they have insurance so that their children will get the best care.

- “Awareness...getting an idea of what influences the health of the child...how the environment impacts your children.”
- “How information is going to benefit me and my child and how that information will help other kids with similar needs.”

When asked who would be a good spokesperson for the study, they that it would be important the tribal leaders supported the study and that they were sure that the study did no violate any aspect of tradition. They also thought a doctor or a celebrity who is a Native American mom would be good spokespersons. Word of mouth is also a good way to spread word about the study.

- “Knowing that tribal leaders are standing behind the study...It opens doors...It is ok to share information in the study, because it is going to be a certain period of time and does not go over any traditional aspect.”
- “If it is pertaining to Native American women, a celebrity who is a woman and Native American...Definitely be a mom. She has to know about children.”

They said that they wanted the study to contribute to their child’s health, the Native American community, and public health overall. They expected to get information so that they would know what types of health programs are available to their children and their community. Most important to these women is that the information learned in the study be passed on to the tribal leadership to educate them. They felt that although “it is a national study, it should improve life in the community.”

- “Information to be passed on to leadership...how to improve and change conditions in the community...They [leadership] don’t want to address the social issues...Maybe this study will convince them...A national study but [it will] improve life in the community.”

The group indicated that it was as important that the study contribute to the health of the community as it was that the study benefit their child. One woman said that it was important that Native Americans were being included in the study, because they said Native Americans are often left out of studies. Others group members concurred with this by nodding their heads.

- “To me, I think it is important just that Native Americans are being included. You never see Native Americans...Native Americans are never mentioned... Yes, we are a people. We belong in a study just as much as anybody else does...I don’t pay attention to studies. I think we are left out a lot.”
- “What is available to your children and the community?”

Part 2: What About the Time Commitment and Data Collection Activities?

None of the women objected to the level of participation presented. The women said that they would be comfortable maintaining this level of participation for the duration of the study. They said that the visits were normal and they were already doing them for their children. If they could still see their

regular doctor, that would make them more comfortable. But they liked the idea of having a second doctor from the project involved, so that they could get a second opinion. However, they did say that it would be important that the project doctor remain the same throughout the project, so that they could build a trusting relationship.

The women assumed that by being in the study, they would spend more time with doctors than they do now and get more care for their children that they found desirable even if it meant making extra visits. If the study provided transportation, that would be nice, but it was not expected.

- "I'm already doing all this now with my son."
- "If it was from pregnancy to now, I think I would have a lot of information...your child's health is your number one thing."
- "I like having a primary doctor and a second opinion."

Group participants did not have a problem with allowing collection of tap water and dust. What was important was receiving feedback. Environmental studies of water had already been done in their communities but they had never received the results. They were divided on whether they would rather do the collection themselves or have someone come in. If they did it themselves, there was the concern that they might not do it accurately.

- "They have already done that in our community...What they do with the samples we have never really been told. We want some kind of results... Is our neighborhood safe?"

The group members said that they would have no problem completing a questionnaire. They liked the idea of doing the survey by email or by logging in to a web site. One person preferred to do the survey over the phone. They did not want to receive the survey by mail because they would procrastinate in completing it.

The women were open to providing most of the biological samples. They wanted to know why the different testing was being done and they would want to receive the results of all tests. As for giving blood and urine samples when they were pregnant, they said they do that already. The women said that they would be willing to give umbilical cord blood, but would also like to have some of it stored for later use if necessary. The women did display a sense of mistrust here as they thought doctors already did something with the umbilical blood without telling them.

- "The cord blood, they can [take] that anyway, if the doctor suspects something is wrong, it's at the doctor's discretion...It is probably done anyway sometimes without consent...If it is going to study the health of my child, then yes."
- "It is important [because] certain diseases are coming into the community. Leukemia, cerebral palsy...I think it would be important [to keep the cord blood]."

The group would provide breast milk as long as they could collect the sample themselves privately without someone watching or waiting for them. They liked the idea of having their own breast pump.

The women were also agreeable to providing the meconium sample noting that it be thrown out otherwise. The women would agree to allow a technician to take a buccal cell sample from their child, but would want to be there. Similarly, they would allow the doctor take blood and urine samples from their child. They said that their doctors already take buccal cells, urine, and blood samples from their children when they are sick. The group participants were mixed on whether or not they would give up baby teeth. One person wanted the teeth back, others said it was okay as long as they knew what the teeth were being used for and only if one or two teeth were taken. They had no problem giving their child's fingernail clippings.

- “I wouldn't mind the teeth...It is not such a big issue as hair. It is still part of the body.”

Genetic testing was also acceptable if they received the results.

- “I would be ok...My oldest son was sick a lot...They said it was heredity. But I never had any testing.”
- “If they find any abnormalities, test myself and the father as well.”

There were two types of biological samples that the women would not want to give—placenta and hair. The reasons were not physical, but rather spiritual or cultural. The placenta is traditionally used in a ceremony to protect the child. They said that they wanted to show respect for their traditions, and if they agreed to give up the placenta, they wanted the testing shared with their tribal leadership. There was a need to “balance values—the traditional cultural and for health.”

- “No, [not the placenta] for traditional reasons, cultural purposes... [We] use it in a ceremony to protect the child for life.”
- “For me the cultural traditional aspect is first, over science...Just being a mother in our tradition...A baby is connected to you... It is the bond, but being a mom is having a special role in the community, a status...But I don't disagree. It's science. I am open to a stem cell study, if it is shared with leadership...For me, the first thing is respecting the culture, then science.”

Group members also had strong feelings also about giving samples of hair. They became quite excited talking about how hair can be used for witchcraft. Most of the women said that they would not give a hair sample. Those who would even consider providing hair samples indicated that they would want to be there to watch the sample being taken and tested and would want the hair back.

- “I am Navaho. With us it would be to prevent witchcraft...If you cut your hair, you burn it. You don't just throw it away.”
- “I would want to watch it.”
- “I don't know anyone who would do it...we are superstitious.”

- “Maybe if it went through one person’s hands only and they were trustworthy.”
- “It would be better if the hair was returned....You could burn it yourself.”
- “Even in the clinics, to take hair and give it to the nurse, maybe there is some conflict with that person’s family. You would be afraid. Call it taboo...”

All group members agreed that their child should sign a consent form when he is 15 or 16 years old as long as the child can understand the conditions. The group agreed that before that age, consent is the mother’s decision. “When they are 10, you are more of a parent.”

Part 3: How Do We Keep You Interested?

The women thought that receiving gifts for participation was appropriate. They liked gift certificates more than coupons and suggested that gift certificates for diapers, clothing, or school supplies for the child would be good. They particularly liked the idea of receiving a gift certificate for school supplies at the beginning of the school year. Gift certificates to national chain stores, especially Wal-Mart, were best. They said it was also important to have something to the child when they turn 18 or 19. There should also be something to acknowledge the mother’s time. They did not like the idea of receiving a gift for giving a biological sample. Gifts should get bigger the longer they are in the study. People who stay in the study over the long term should be rewarded.

- “For me at the beginning of the school year...go to Home Depot for school supplies.”
- “Information is always useful. Sometimes they don’t give you information.”
- “Something for the mother because you are taking time...a spa day or pedicure.” (They laughed about this.)
- “Not get a gift for a sample.”
- “Not something outrageous, but something for the child, especially as they get to be 18 or 19...not a laptop [they thought this was silly]...a scholarship for education.”
- “The gifts should get bigger the longer you are in the study, especially for the 21 years...reward people who stay in.”

In general group members were not excited about receiving cash. They preferred that the money be tied to things. However, the idea of getting the money and being able to use it for whatever things they needed was appealing, as was the use of larger sums of money for education.

- “Give options...get one lump sum for clothing, or if you are not concerned about clothing, something else.”
- “Money for savings accounts, scholarships for the child...tie it to education, their future.”
- “Tie the money to these things...not just cash.”

Group members thought that there was a possibility that receiving a big incentive might make you feel you had to stay in the study. They also said that it would be easier to leave the study when the child was younger, before you have invested a lot of your time and the child’s time.

- “If [it is] something big like a computer, I think you probably feel compelled...[you] would feel more prone to stay [in the study.]”

The women made a distinction between receiving personal information and general information about the progress of the study. They all indicated that they would like to receive feedback on the testing right away. Information should be available at the time of the doctor’s visits or by calling a telephone number after a test. For general information, they especially like the idea of receiving a newsletter or having a meeting with the researchers and participants. Newsletters would be good because you could refer to it again later. They would like to receive the Newsletters every three to six months. Newsletters should describe the progress of the study and should include information on what to expect before you go for testing.

- “I thought it would be after each time you took your kid.”
- “Able to call a phone number to get a result.”
- “I think a newsletter is a broader source of information...You can go back and refer to it.”
- “I would prefer a meeting [to a newsletter]. If you have a meeting once a year to know who is in the study.”

There is no information they would not want to receive, even if the results could not be interpreted. That way, they might be able to prevent something like heart disease by changing their lifestyle or diet.

Part 4: Barriers to Participation

The women indicated that for them to agree to participate they would have to feel comfortable with the study and feel a sense of trust. The women mentioned that they did not trust the government because the government had promised them things in the past and had not delivered. There was also a concern that the Indian Health Service might do secret research. They wanted to know what the government was going to do with the study results. The women said that they would need to be kept informed throughout the study about any risks to their children. The women also wanted to be assured that their names would be kept confidential.

- “I think it would be okay as long as you were comfortable with the people and you had understanding...you will not want to share personal information if you felt uncomfortable.”
- “Government sponsor? I am a little uncomfortable. What is important is how they are going to use the information...And you are informed at every step what is going on and you are not left out.”
- “Because of history...we have been promised so many things...but it hasn’t been given. We want the outcome. How are they going to help us and how are we going to sustain our people?”
- “It is an all too familiar story. My grandmother was diagnosed with diabetes...She takes 20 different pills and half the time the pills make her sick. Are we playing the guinea pigs for the Indian Health Service?”

In addition, the study protocols would need to respect their traditions. It would be important for the tribal leadership to be involved to facilitate participation among American Indians. It would be equally important for the results of the study to be shared with the leadership. Several of the women expressed an interest in educating the elders.

The women suggested a number of steps that the study could take to address their concerns. First, the study should guarantee their confidentiality and privacy. Second, they wanted the researchers to act as a network to help them get health information and get in touch with experts. Third, there should be a promise that programs that would benefit them and their communities would result from the study. The group discussed what the study should be responsible for in the event that they found a health problem in a child. The consensus was that the study had the responsibility of giving them information, sending them in the right direction to medical experts, but not paying for or treating the problem. Finally, it was important for the study to show that they will develop programs for the community based on the research results.

- “How the study could help you get in touch with experts.”
- “If it wasn’t caused by them [the study], I wouldn’t expect them to treat it.”
- “At least point them in the right direction to get help.”
- “They need to explain how far the risks are going to go with the study.”
- “What are they going to do with it? What are they going to develop from the information? Benefits not just for Native Americans, for all people.”

One person said that you have to have trust if you are going into a study like this.

- “With any study, if you agree, you are going to take certain risks, whether it is finding out if your child is susceptible to this kind of disease or your own issues about confidentiality. You have to have some trust when you go into a study...If you don’t have trust and it is going to stress you out, you shouldn’t get into the study. Trust yourself to trust them.”

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3.1.8 Seattle American Indian (Pacific Northwest) Focus Group Summary

This focus group with American Indians was held in Seattle in December 2003. Seven women participated in the group session. The women were identified with a number of tribes: Tlingit, Nooksack, Nisqually, Fish River, Cherokee, Klinket, and Sioux. None of the women currently lived on a reservation. All were parents of young children but none of the women was currently pregnant. Five of the women reported that they had 1-2 children and the other two women had 3-4 children. Three of the women had children less than 3 years old, five of the women had children 3-5 years old, and three of the women had children 6-11 years old. Six of the women were aged 26 to 35, and one was 36 to 40. Six women had some college and one was a college graduate. Total annual household income ranged from \$10,001 to \$30,000 (1 woman) to \$30,001 to \$50,000 (3 women) and \$50,001 to \$75,000 (3 women.). Two participants characterized themselves as living in urban areas, three said that they lived in a suburban area, and two women lived in a rural area.

Part 1: How Do We Get You Interested?

Group participants said the best places to hear about the study would be the doctor's office, the Health Department, the Indian Health Service, or a community or tribal center. They liked best the idea of their doctor telling them about the study or giving them a brochure. Another possibility was to have a poster about the study or a flyer that they could take with them. They suggested also that the Indian Health Service could talk to people who come in about the study. For recruiting Native Americans they thought that besides the doctor, the tribal agency would be the best way to recruit. They also mentioned an organization called Native American Families Together.

- "If it [the information] came directly from the doctor."
- "For Native American women, it is best through the doctor's office or through a tribal agency."

The women mentioned a range of media for getting word out about the NCS. For reaching Native American women they said the tribal newsletters would be effective. They also mentioned magazines such as "Parent Magazine" or "American Baby" (which you sign up for at Toys R Us and Babies R Us) or a free paper like "Northwest Child." They were divided on whether or not the study should advertise through newspapers. Most preferred advertisements in the free paper "Stranger" over the Seattle newspaper. But one person said she was "leery of the other [free] papers" and another did not like the idea of using the newspaper at all. Some of the women said that they never look at the ads in newspapers or magazines. They thought that an article would be better.

They did not think TV would be a good mode of communication because they don't have the time to watch it. They also reported that a web site would not attract their attention and if they had to go to a website, they felt it would be too hard to find. They did not like the idea of advertisements on buses, telephone calls to their homes, or unsolicited mail. If a piece of mail looks like a "piece of solicitation," it goes in the garbage. With phone calls they would not know if the person calling was legitimate. "How would you know?"

- “I read my tribal newsletter.”
- “It needs to be an article that describes the study, coming from the medical field so I know it is valid.”
- “A lot spread by word of mouth.”

Before contacting the study, the most important things the women would want to know are the benefits and risks. Another important piece of information would be who is endorsing the study and who opposes it. Other information they would need to know before they called included the purpose, qualifying factors, what they have to do, the compensation, how much time it would take, and whether they would have to drive to Seattle each month.

- “It is important [that there are] benefits to children...Our own kids and people or kids in general.”
- “Who endorses it, if there is anyone against it.”
- “I would be more concerned about my child, the risks.”

Group members said that it was more important that the study benefit their children than contribute to public health, and all but one thought the spokesperson would be important. Some thought that a well-known person with credentials like Dr. Spock would be a good spokesperson. Others liked the idea of having a local health care provider or familiar face as a spokesperson, particularly someone that could represent Native Americans.

- “I am uncomfortable with a spokesperson. They are just marketing.”
- “A pediatrician [who is] renown, has good credentials.”
- “It would have to be a familiar face.”
- “A health provider, a local person.”
- “Someone from my tribe. If he asked me to do it and says it is important to our kids, I would do it.”

The women thought that it was more important that the study improve the health of children (not just their children) than that it contribute to science or public health. The women mentioned that they had trust issues with the government. They were concerned that Native Americans would not be included even though the government said they would be included. The idea of contributing to science scared them. They wanted the results of the study and were concerned about their privacy.

- “Improve the health of children...not just my child, but children in general.”
- “A lot of Native American people are sketchy when it comes to anything to do with the government...If they say it is geared to Native American children, then it has to be true.”

Part 2: What about the time commitment and data collection activities?

Asked whether they would be able to sustain the level of participation presented, some thought that four doctor visits in year 1 was too many, but two visits would be alright. They preferred that the visits coincide with their regular doctor visits. Whether they could maintain this level of participation

would depend on what the compensation was, how much time would be required, and how far they would have to travel for testing.

- “Four doctor’s visits just for the study? That’s a lot.”
- “If it’s tied to your own doctor visit.”
- “That is really not that much, if it is a provider I can get to easily.”

When asked to discuss how they felt about the collection of water and dust samples, the women indicated that they would need to know why the study wanted to collect tap water and dust and what was going to be done with the samples. The term “environmental samples” made them uneasy. The concern was that they would be deemed an unfit parent and reported to Child Protective Services (CPS) if the study found something wrong in their home environment.

The women wanted the option of collecting the samples themselves but were divided over their desire to have the flexibility in their schedule and their concern that they would not perform the collections correctly.

- “[Saying] collect environmental samples is scary. Say collect tap water and dust is better...If they say it is an unhealthy environment for your child...you are an unfit parent...I have to know it is EPA not CPS.”
- “How do you know what they mean by ‘environment’?”

The women had no problem with completing a questionnaire but would not want to do it more than two or three times a year and clearly desired flexibility in the mode. They wanted a choice of mode—Internet, telephone or mail. Those who preferred telephone, would like to have the survey scheduled in advance. One person said she would toss out a survey that came in the mail, while another said that she preferred mail because with small children there are many distractions and she could do it when she has time.

Asked whether they would give blood and urine when they were pregnant, they initially said they would not do it. After some discussion, they seemed more willing but would need to know why the samples were being collected and what the researchers were going to do with them.

- “No way. I’m not doing it.”
- “Too much private information.”
- “I would need have to know why, where is it going...who is getting this information from me.”

With the exception of one woman who wanted to know why the study wanted her placenta before she agreed to give it, the women did not want to give up the placenta. There were several reasons for this. One reason is that Indian women keep their placenta and do a ceremony with it. Another reason is that they did not want their insurance knowing their medical information. Finally, they were afraid that the researchers would perform other tests without their consent or knowledge.

- “A lot of Indian women keep their placenta...A lot of women think it is sacred...They do things with it.”
- “I am very skeptical. I don’t want my insurance knowing my medical information.”
- “I don’t want you taking anything extra...How do you know?...How do you know they take this and this?”

In response to the question of whether they would give umbilical cord blood to the study, they asked whether that is where they get stem cells. They said they would have to know exactly what was going to be done with the sample beforehand. One would want the umbilical cord blood stored in case it could be useful to the baby later. Some were concerned that even if you signed a consent form, the study could change its course and they could do something else with the samples.

- “You have to have the doctor sit down and say this is the test we will do... You have to do this initially, so when they ask, you won’t be shocked.”
- “Part of the consent? Can’t studies change their course? You could have signed something and then there is a change.”

This group of women thought that it was “weird” to give away their breast milk since it would not be used for its purpose, which is to feed the baby. However, they seemed willing to give the sample if they could give it to their own doctor. They disagreed on whether 2 ounces was too much milk to pump or not. Finally, they wanted to know what would happen if they found something wrong.

- “When I’m pumping, I would be anxious about giving it away to a stranger....it is important to have it with your own medical practitioner.”

The women were also curious about the meconium sample but did not have a problem giving the sample because it would just be thrown away otherwise. Again they were concerned about results that showed something wrong with the child. They want to be informed if something is wrong so that intervention can take place.

Group members had no problem with allowing their children to provide blood and urine, as long as the parents understood what tests were being conducted. The women also expressed a preference for having the study sample be drawn at the same time as a regular draw might be needed if possible to avoid having the child be stuck twice. For example, the women said that they would not agree to a blood draw in addition to a heel stick.

The women did not want to provide hair clippings but did not mind providing fingernail clippings. The women noted that hair is sacred to their people and part of the body. Fingernails are also a part of the body. If they gave these samples, they would need to know what the samples were for. They would also want to be sure the samples were in the right hands and that they were destroyed after they were used.

- “I am answering for my people. Hair is also very sacred.”

- “Fingernails—People would think it strange because it is part of the body.”
- “I don’t want them to keep the samples...destroy them.”

Asked whether they would give buccal cells, they said “That’s DNA, no!” The only experience they had with buccal cells is for DNA tests. But one person in the group commented that DNA was in everything. They were not concerned with the invasiveness of the test.

Group members all said that they would not give the baby teeth. One person said the study could have part of a tooth, but the others said no.

- “The tooth fairy gets them.”
- “They can look at the teeth in their mouth.”

These women were generally opposed to giving genetic information. The exception would be if the testing would save a child’s life or if the child had a rare disorder. Most of the group was concerned that their privacy would not be kept, the information might get in the wrong hands (such as the insurance company), or that the pharmaceutical companies would make money off of their genetic information. If they allowed genetic testing, they were divided on whether or not they would want the results.

- “I don’t like that. I think it could get in the wrong hands...Insurance can get it.”
- “I don’t want this [information] floating around if I couldn’t control it.”
- “They may single you out. If my child is predisposed to diabetes, when he is older, he may not be able to get insurance.”
- “How can you guarantee my privacy 14 years from now?”
- “If it is going to save someone’s life, ok, I wouldn’t mind going to the trouble. If it is going to large pharmaceutical study just to make money, no.”

While one woman thought the child should sign a consent form at age 16, the others thought 18 was the appropriate age. There was disagreement about whether a younger child should have a say in whether he would participate. One said that if the child does not want to be in the study, the family would leave the study. Another said the parent and child should discuss participation. A third person said that she would review the pros and cons and make the decision for the child.

- “Both child and parent through the young ages should say yes...If my kid at 11 doesn’t want to participate, we are gone.”
- “A dialogue with my child...I envision we have that conversation every time we go.”
- “If I’ve agreed to the study...with my kids, what I say goes and you are going to do it. I have already looked at the pros and cons.”

Part 3: How Do We Keep You Interested?

Group members liked the idea of getting gift certificates for participation. Gift certificates for the Gap or Safeway would be good. They did not like coupons, because you have to put up some of your own money. One person said she would not participate if all she received were gifts because too much time is required. Another person thought there should be a gift for both mother and child. While one person said

she would participate to know what the study results were, others said the study required too much time for them to participate just to get the results.

The women liked the idea of the child receiving a gift and the parent receiving gas money for each visit. Gifts for visits were important because the child may be afraid of needles and the parent must spend her time to take the child to the visit. They also suggested that coupons were a good incentive for doing the survey.

- “For me as a parent it is the time. For my child it is the thing. Something for both.”
- “Coupons are good for the survey—for photos, Target...A coupon in the survey. A little thing.”

There was a lively discussion and a variety of opinions expressed on the issue of whether money should be given for participation. One person did not want money because it would feel she was selling her child. Another just wanted compensation for gas and time. Others wanted cash and wanted the amount to be agreed upon up front in a yearly contract. Two people had participated in other studies and wanted the amount to be competitive. There was also discussion of whether they should be paid if they are volunteering.

- “A check. That really bothers me. It sounds like I am selling my child’s blood.”
- “Just compensation for gas and time. No more than that.”
- “Placenta, blood. These things are not easy to come by. It doesn’t seem you can put a price on any of these things.”
- “Money is not a high priority in my family. [What is important] is living a positive lifestyle.”
- “Maybe \$25 an hour. I would compare it to the study I did as a child. Each of us was compensated”

Group members did not think that any particular amount of money would make them feel they had to participate. They said that if they became uncomfortable and wanted to quit for any reason, they would just quit.

- “If I got uncomfortable, you could kiss some part of my body goodbye.”

The women wanted to receive generalized information about the study and personalized test results. It was important that they receive information before the general public received information. They preferred that they have the choice of which mode of contact—telephone, Internet, mail—would be used to contact them. They also liked the idea of a meeting with other study participants and researchers.

- “If there is a break through on the study, I don’t want to find out on the news.”

They would want information 2 to 4 times a year. A quarterly newsletter and an annual or biennial meeting would also be appealing. Group members would want to know about all the tests that would be run, what they are looking for (e.g., lead), and how the results will be used. They would also

want specific information on the effects of various environmental factors on different groups of people. There is no information they would not want to receive. One woman said she did not want to know the genetic results if the study could not do anything about them.

- “Provide a packet. These are all the tests we will run.”
- “I am still leery about what you are actually doing with the information...It must be detailed and specific. We have to know what they are looking for.”
- “I would have to have the specific purpose...the effects of this on this group of people before I signed on.”

Part 4: Barriers to Participation

The group had many concerns about participation. First, they were worried about the study being a government study. In their view, the government has a hold over any organization, such as the universities and hospitals that get government money. They worried that even if they signed a consent form, there could be changes in the study after the fact that they would not be aware of or could not change because they had already consented. They wanted to be assured that the information would be used only for health purposes and not to harm people. In terms of activities that the women did not want to perform were the collection of the placenta, hair and teeth.

- “The National Institute of Health? If it gets money from the government, the government has a hold on them.”
- “You say you will do one thing and instead you do something else. There was a researcher killing mice when he was not allowed to. They arrested him. He was torturing the mice, giving them medicines they weren't supposed to, without permission.”
- “You have a smelter on your property and the soil is poisoned. If they find out, they can't use the information to harm the family...and screw up your insurance...[There is] a specific use of the information and you can't change that.”

The group made many suggestions for things that the research team can do to address their concerns. First, they wanted an overview of the tests that would be run and the reasons why. Second, they need to know the results, where the results of tests go, and how they would be used. Would the study help remedy environmental problems? Third, they wanted enough information to determine if this is a good study and that it is not just being done for financial gain. Fourth, they wanted their doctors to be an integral part of the study. Fifth they wanted checks and balances in the form as a community advisory board. Sixth, they should hear about the study through the tribal government.

- “An overview of what tests you will run and what for and what will you do with it...If you find a big break through with lead, so what? What are you going to do with it?”
- “There is hundreds of studies and nothing comes of them. They are shelved.”
- “The government has lied, not just to native peoples, to all people. That is why there is so much mistrust of the government. It may not be the government but it

feels like the government. Take the time to explain. This is what your participation has contribution has led to.”

- “If people from all cultures, not just one agency are collecting the information...Checks and balances... A community advisory board.”
- “I would like to hear about the study through my tribal government. This is reasonable or not reasonable. This is acceptable, not acceptable.”
- “People might be just doing the study for financial gain. I don’t know if it is a good study.”
- “If the doctor really know in depth about the study, I would be more inclined to trust them...I need to know if my doctor is just a go-between.”

3.2 Pregnant Teens and Teen Mothers Focus Group Demographics

Demographic Characteristic	Chicago N=5	New York N=9
Age 15-19	5	9
Pregnant Yes No	1 4	5 4
Number of Children None 1-2 children 3-4 children 5 or more children	1 4 0 0	5 4 0 0
Ages of Children* Less than 1 year old 1-2 years old 3-5 years old Older than 5 years old	3 2 1 0	3 1 0 0
Hispanic Yes No	0 5	6 3
Race American Indian or Alaskan Native Asian African-American or non-African-American Black Native Hawaiian or Other Pacific Islander White Missing	0 0 4 0 1	0 0 3 0 1 5
Highest Grade or Year of School Completed Less than high school High school graduate Some college College graduate Graduate school	2 3 0 0 0	7 2 0 0 0
Total Annual Household Income \$10,000 or less \$10,001 to \$30,000 \$30,001 to \$50,000 \$50,001 to \$75,000 \$75,001 to \$100,000 More than \$100,000	4 1 0 0 0 0	7 2 0 0 0 0
Area of Residence Urban Suburban Rural	5 0 0	9 0 0

* Some women had children in more than one age category.

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3.2.1 Pregnant Teens and Teen Mothers Focus Group Summary Report (NYC)

The Pregnant and Teen Mothers Group was conducted in December 2003 in New York, New York. Eleven pregnant or teen mothers were recruited and nine attended. Four of the participants were age 15 to 16 and five of the participants were age 17 to 19. Six of the participants were Hispanic and three were African-American. Seven of the participants had completed some high school and two had graduated from high school. Five of the participants were currently pregnant and four of the participants had a child less than one year old.

Part 1: How Do We Get You Interested?

Participants suggested several ways to communicate with teens about the NCS. The group agreed that they would open mail from the NCS if there was a recognizable logo to identify the NCS mailing. "I'd open it if I knew what it was."

The group also recommended sending representatives to hospitals and clinics where pregnant teens get health care and displaying posters and flyers in "schools where they have day care centers."

Though later in the conversation a consensus of teens agreed that newsletters would be an appropriate way to inform them about the study, when initially asked by the moderator about this option none of the participants thought it would not a good way to reach teens. When prompted, one teen thought that signs on buses and other public transportation would be a good way to inform teens about the study. A teen mentioned the March of Dimes as an organization they think of when they think about being pregnant.

The group mentioned a few important issues they would want to know before calling or contacting the study staff. They would like to have enough information to motivate them to call to ask about enrollment. Specifically the group mentioned information about eligibility and who would be sponsoring the research.

Although the group initially indicated that sponsorship information would be important, several changed their minds and said, "it doesn't matter" and "it's not so important." When asked why sponsorship would not be important to know up front, teens indicated that they would assume that the study was legitimate. "Assume legal and for a good reason." Two teens responded that they would be comfortable calling a toll-free number for more information on the study.

In terms of what they would find most interesting about participation, one teen wanted to know about the "benefits, what exactly it is that's going to affect my child." Two to three other teens agreed that they would want information on the benefits and expectations of the study.

When discussing an effective spokesperson teens mentioned Whoopi Goldberg and Oprah Winfrey. One teen suggested Oprah "because she has a cable channel, Oxygen, and it's more towards women." The moderator asked the group about the singer Erika Badu (because she's young and recently

had a baby) and three women said that the performer would not be effective because “she’s too ghetto.” Further providing, “It has to be someone who makes more of a contribution than others, but age doesn’t matter.” When asked about young non-famous mothers acting as a spokesperson, three teens felt this type of person would not catch their attention. Instead they would assume that a non-famous spokesperson was a model.

When asked what they would like to see come from their participation, two young women summed it up by stating:

- “That something’s actually being done, that you didn’t just participate for nothing and you haven’t seen results or nothing. People talk a lot, but they don’t do much. I think that they should act and not just talk.”
- “That your voice was heard.”

When asked how to provide participants with updates these two women agreed that regular updates or letters would be important.

When asked how they felt about agreeing to participate in a study that was to last 21 years, the teens noted common concerns about the length of time and what would happen if the study were to end sooner, but more interesting was the concern that children don’t live at home until they are 21 years of age.

- “Isn’t that unrealistic to be coming to someone’s house until they’re twenty-one, because some children just move out?”

There was consensus from the group that once a child reached a certain age, he/she might not want to continue participating in a 21-year study. Comments included,

- “But what if the kid doesn’t want to participate? I can’t predict what my son’s going to want. He might be like “‘I don’t want to participate.’ Maybe he’s not going to be the cleanest person on earth. Maybe he would be uncomfortable, that’s what I’m trying to get to. He might be uncomfortable with people coming to his house and he had no part of doing it, it was my idea. What if he was against the research?”

Fifteen or sixteen is the age that teens believe children would start to show some resistance to participating. The moderator continued by asking the group how they would respond to their child if he or she expressed concerns about participation. Several teens agreed that the mother should be the one to explain to the child the importance of the research and that the child is doing something that is good. However, one teen suggested that the researchers also provide assistance to the mother in explaining the study and conveying its importance.

Part 2: What About the Time Commitment and Data Collection Activities?

When asked about the time commitment and number of visits, two teens indicated that two additional doctor visits and one home visit a year would not be a problem for them. However, another

teen offered, "maybe now we think that it wouldn't be a problem, but maybe it would get frustrating at times."

Another teen expressed real concern about home visits:

- "It might be a problem with some people because you don't really know what's going to happen. Like if your house is not clean and you're not taking care of your kids right, or you think you are, but they (the representatives coming for the sample) may not think you are. That's the only thing that would scare me if I was in that situation. It's like my house is dirty and my kids are running around dirty and nappy headed, not clean. They (the representatives) would think 'what's she doing with her child.'"

At least one additional teen voiced agreement with this statement. When asked what the study could do to address these types of concerns, one teen offered that "they should make an appointment because they don't know if the person is working." The teens were very concerned that study staff may show up unexpectedly and report on the care of the child and conditions of the household to the authorities. It became clear that some of the teens were relating the term "home visits" with the type of visits a social service agency might make to evaluate the care of the child and the living conditions. The moderator emphasized that the purpose of the home visits would be to collect samples of house dust and tap water to evaluate the environment. With this clarification, the concerned teen indicated that she would be comfortable with representatives coming to the home to collect samples.

The group did not address whether they would be more comfortable collecting the samples themselves using a kit. Once again, the group started to discuss how some people who might not be "taking care of their kids...could lie" if they collected the specimens themselves. She suggested that the study staff make a number of home visits and then allow self-collection only after the participant has earned the trust of the study staff. At least two teens agreed with this statement.

- "I think after a certain amount of home visits, certain people coming and you gain their trust, I gain their trust, they [the participant] should get the kits and send it [the samples] in."

The group agreed that completing the survey 2 to 3 times a year would not be a problem. They also agreed to the collection of both blood and urine during pregnancy.

The group also agreed that tests could be performed on the placenta after birth. In fact two members of the group believed that tests on the placenta were currently performed without the mother's knowledge. The group also would allow the collection of cord blood.

There was some confusion over the collection of breast milk with only two of the teens indicating that they had breastfed their babies and would have no problem providing breast milk samples. Another teen asked, "How small [of a sample]? Because that hurts, that hurts I don't care." Another teen offered that the milk would probably be extracted using a breast pump and this teen responded, "no, because it hurts." Several other teens laughed and giggled about the teen's concerns about pain. Other than the two

teens who indicated that they had breast fed their babies, no others indicated that they would be willing to provide breast milk samples. Other questions included, “What’s it for” and “Do you just do it once, just once to provide the breast milk”?

Meconium collection was not an issue for this group but collecting blood and urine from the children raised some concern. When asked if they would agree to let a nurse collect blood and urine samples from the child, the responses were mixed with some teens voicing a sense of not being on control and others with very little concern about the sample collection.

- “It’s going to happen regardless”
- “I’m fine with taking all the samples, it would be fine. I’m not even concerned”
- “Not too much blood”

The group wanted to clarify whether the sample collection would be done by another doctor or their primary care physician. One teen asked, “Would this be with a separate doctor?” Two teens suggested that the participant’s primary doctor collect all samples. One teen offered, “That would be more convenient having your own doctor sending it for you.”

The group agreed that they would allow samples of hair and fingernail clippings. One teen indicated that the mother should be the one to take the samples and bring them to the office or lab.

After the moderator provided an explanation on how buccal cells are collected, a consensus was reached that they would allow the collection of buccal cells.

When asked how they felt about providing one or two baby teeth, several of the teens agreed that they would provide a few teeth as long as they were not asked for the baby’s first few teeth. One teen tried to point out that giving up one or two teeth was not a big deal. She laughed and said “One tooth come on, they have about 100.”

- “I don’t know about the baby teeth”;
- “Yeah, you don’t want to give those up”;
- “Not baby teeth. I’m not with the teeth. After they fall out, ok”;
- “No, they have sentimental and emotional value”;
- “Some people just keep it, they put them inside those little books.”

The group voiced little concern when asked about agreeing to genetic testing which may have been directly related to their lack of knowledge about genetic testing and what is involved.

- “Doesn’t bother me”;
- “Is it just blood drawing and that’s it.”

When prompted by the moderator, two or three teens offered that they would have some concerns regarding confidentiality. The consensus was that they would want to know the results of genetic tests and would be more likely to agree to tests if they received results.

When asked at what age they thought their child could provide consent to participate, three teens said 18 years of age; one teen said 15 years, and another said 15 to 16 years of age. Responses and debate about the age of consent included the following comments:

- [AT 15]”They don’t make up their own minds yet. You [the child] still under my [the mother’s] care”
- “I don’t think they make the right decisions [at 15 years of age]”
- “I might sign something that I don’t know fully. I’m fifteen, I don’t want to sign something that it could come to haunt me as I grow. No, I say 18 when I’m legal”

Another teen was in support of a child providing consent at age 15. This teen argued that a child could make a decision to participate if he or she felt like participating. She did not understand the importance of collecting the data at the scheduled intervals and was under the impression that visits could be ‘made up’ at a later date.

- “I think they should make their own decision at age 15, 16, the same way some of us are doing because by that time they would be open minded.”
- “They know what’s good, they know what’s bad. I think they would know what they were doing (at 15 or 16 years).”
- “They could always come back [if they skipped a year or a visit]. If they feel they don’t know what they’re doing they can always come back when they’re older, say 18 years old and redo it again [meaning their participation]. If you bring a child in when they are 15 years old to look at something and the person doesn’t understand it, another appointment is made.”

Another teen offered, “I feel it should be 18 because most of us are still under our mother’s care and supervision and you don’t make your own decisions. I [as mother] make your decisions for you until you are 18.” Two to three teens responded in agreement to this statement about being 18 years to sign a consent form.

One teen who was supporting the argument that a child should be 18 before signing a consent form added the concern that signing a document might have consequences in the future and even though she has become pregnant at an early age it does not mean that she wants to take responsibility for signing something that she doesn’t fully understand nor would she want her son to sign something that “could come back to haunt him.”

- “Even though some of us are pregnant at the age of 14, 15, whatever, it has nothing to do with signing no papers that’s going to haunt me even though I have a responsibility [a child]. That’s not like signing a paper and it’s going to come back. Say if I was to join the Army at 15, that’s going to come and haunt me because I have to do certain time. I don’t want my child having nothing haunting him.”

One teen noted that the study is voluntary and that a participant can choose not to participate at any time thus there are no long-term consequences

- “But there is nothing forcing you to do it, if you want to leave, you can leave.”

The moderator asked for a vote from the group on the age of consent. Three teens believe that the child should be 15 years old when signing the consent for him or herself and six teens believe the child should be 18 years of age.

Part 3: How Do We Keep You Interested?

After reviewing the suggested incentives on the show card, one teen responded, “These are good, very good, very good.” Several others teens follow with agreement and offered that they would sign up immediately. All agreed that the incentives would be appropriate for participation in the study.

- “No offense, I know this is going to sound weird, but I think the whole cell phone and cable is a little to much. I want them, don’t get me wrong, I want them, but I think it’s kind of gaudy.”

The moderator asked whether they thought that these incentives would be appropriate for the child once he or she is a teen (15 years of age) when they are less interested in participating in the study. Several of the group members agreed that these items could encourage a child to participate.

Another teen was concerned that the offer of such gifts would be coercive.

- ”But I don’t feel you should be bribed. “Oh sign this because you’re going to get this, you know”? I think it should be certain things for a baby, like coupons and gift certificates when they’re little. As they get older, the electronic stuff is okay, but I don’t want him to be bribed like, come on baby, come on baby, sign this because you’re going to get a cell phone and cable for the house.”

In response, the other group members felt that they would still have a choice about whether to participate. The group agreed that the most beneficial gift would be a scholarship or college tuition. The group did not believe that the test results and health information was an incentive, but rather it was an expectation that they would receive the information.

- ”The government paying for college would be a very good way to give something back to the community.”
- “Information about your health and your child’s health should not be an incentive.”

One of the teens suggested that participation could be reported on a resume since this would be a very important study.

- “An incentive not provided on the list is the ability to report your participation in the NCS on one’s resume because it would be a very well known and prestigious study. It would show a sense of community responsibility and the fact that you can keep a long term commitment.”

One teen shared that she felt that the requirements of the study should be provided in detail at the beginning of the study. If a person agrees to participate, then the person is agreeing to participate in every phase of the study, including providing these samples.

- “I think it’s [sample collection is] included in [the] research. If you have to do it to be a part of it [the study] then you have to do it.”
- The group agreed that money was appropriate as an incentive.
- “Yes, it’s [the money] towards your children. Ok, say your child was inside the NCS for like five years or something, they should get money towards their college education. Not like just giving you money like yeah, you need \$500. It only goes to the child, it’s for the later generations. It’s not for us, it’s for them. We are not supposed to be getting benefits from this. This is supposed to be benefiting us by knowing our child is safe and everything.”

Two teens voiced agreement with this statement. While another teen agreed, but also felt that the mother should get some benefit or assistance with college. When the moderator asked the amount of money they felt would be appropriate, responses included:

- “A lot”;
- “Maybe some money at Christmas time because that’s when we’ll need it, we’ll have kids. That would help us out a lot”;
- “Like a buck (\$100.00) or something, you are examining my child”;
- “From the government, it should be \$5,000. You know how much they get? They take from us a lot so they could give back”;
- “Help us to pay insurance, like car insurance, health insurance. There is some health insurance that doesn’t cover everything. What if you have a sick baby and your health insurance doesn’t cover everything”?

Another teen responded, “That’s asking them to carry you on their back. If it’s a sickly child and my insurance doesn’t cover everything then medicines and insurance is good instead of the money.”

About half of the group felt that money for the child was appropriate and the other half felt that money paid to the mother would be most appropriate. One teen felt that assistance with insurance would be most appropriate.

When discussing ways to keep participants informed about the study, three or four teens agreed that letters, e-mails and phone calls would be useful. The group did not like the idea of an automated response when calling for information about the NCS. Instead they would prefer to speak with a person. One teen mentioned that automatic telephone systems often leave the caller on hold with no one available for assistance. Another teen suggested that every family be assigned a PIN number for easy reference to their personal information.

Seven of the nine teens are Internet and e-mail users. However, they all agreed that communication about the study should be provided in several options with the participant choosing the option they most prefer.

The information that they would most like to receive in regular updates is information on whether the study has helped anyone and how the study has advanced toward its goals. However, the group did express a desire for “all” information.

- “Has it helped anybody”
- “Everything, where has it taken the research, how has it gotten to the next level”
- “Don’t repeat information and don’t lie either.”
- “I think everything involved in the project is good information. I think that you would want to know everything that’s going on, whether it’s little stupid things or big things, I think it’s all important.”

One teen suggested that the study offer participants a paid job to recruit family, friends and other members of their community. If they were participants, all teens agreed that they would participate in community information sessions to inform others about the study.

Part 4: Barriers to Participation

When asked about specific concerns that they might have about participating, the group listed confidentiality, study sponsorship, and receipt of information.

- “Number one would be confidentiality”
- “Who runs the program (sponsorship)”
- “Receiving follow-up information about you and your child”
- “Boundaries and accountability of the research study: “It should be an agreement not only for us, but for the people who want us to participate”

A consensus agreed that they would want to know exactly what tests are performed and how specimens would be handled and destroyed. Several teens agreed that a copy of the research agreement should be available to all participants.

- “We want to know what’s going to be done with blood.”
- “I don’t know what my son’s going to do when he gets older. I don’t know if he’s going to smoke weed, do crack, I don’t know what he’s going to do. I want to know what he’s being tested for.”
- “If they find marijuana or they find whatever, it is important that it can’t be used against him.”
- “The blood has to be disposed of in the right way, not going into another lab to be tested for another thing.
- “It has to be black-and-white. What exactly is going to happen with the sample, where’s it going to go, what’s going to be done with it, what’s going to happen with it after you’re done.”

3.2.2 Chicago Pregnant Teens and Teen Mothers Focus Group Summary

This teen focus group was conducted in the Chicago offices of RTI in December 2003. Eight teens were recruited, and five attended. All five participants were between the age of 15 and 19. Four were African-American and one was white. Three of the participants were high school graduates and two completed some high school. One participant was currently pregnant; three of the participants had children less than one year of age. Four of the participants reported income less than \$10,000 per year, and one reported income between \$10,000 and \$30,000.

Part 1: How Do We Get You Interested?

The teens suggested having mentors at schools to provide information about the NCS to teen moms. One participant mentioned that it will be hard to recruit teen moms because there is so much prejudice towards them and there are many teen moms that keep it very private and do not want to share their lives to avoid criticism and the stigma.

The group agreed that phone calls were not a good way to reach a teen mom because most of the time teen moms live in "someone else's house" and the message may get lost. The group considered the mail to be a better way to reach them and have a toll--free number for more information on the study.

- "Teen organizations, high schools for pregnant teen, hospitals, clinics, pregnancy centers, community centers such as Boys & Girls scouts, YMCA. Magazines for pregnant mothers, doctors."
- "No telephone calls, mail is better, a web site, TV ads, and public transportation ads"

The group did not consider a celebrity to be a good spokesperson, unless that person was a teen mom herself. The group was concerned that the study would be more an "experiment" than a scientific research study. The information that the group considered to be the most important included: the risks of participation, how much time would be involved and how to have healthy children. The group was concerned about privacy and the history with "experiments" done to black people before. Being part of a national study was attractive for this group.

- "The purpose, the benefits, the risks, if it's an experiment, demographic information such as percent of other races, who will be targeted, the testing types, who is sponsoring the study and how the people is selected, more information about privacy"

The group agreed that the most important thing they would like to see from their participation was "A healthy baby." They considered that contributing to science and to the possibility of helping to find a cure for diseases was important too. One participant was more skeptical about how much impact the results of the study would have on improving people's lives. She indicated that the health of the mother and consequently the health of the baby were affected by their social and emotional environment; unfortunately a study would not stop violence and other social problems. The group agreed that in

general, teen moms would like to learn more about health issues that may arise, mostly, among young parents.

Part 2: What About the Time Commitment and Data Collection Activities?

There was consensus among the group that one hour for the doctor visit seemed too long. They mentioned that the doctor visit usually takes no more than 10 minutes, but waiting may take up to an hour. The group agreed that one impediment to participate would be the need to travel to a facility for doctor's visits, testing, etc. One solution would be to provide transportation for the moms or conduct the study activities at a health clinic in the community where the mom resides. The number of visits and the frequency presented was acceptable to the group.

- “Going to my own doctor for samples and testing, but not to a different health care provider; agreeing to participate for that long will depend of the incentive-how much they will pay; prefer to do it confidential at my home.”

When the group was approached about the environmental sample collection they became defensive. One participant asked: “what is going to be done about if they find problems in the community, improve the water?” The group considered that the number of home visits once a year was okay, but they thought that doing it every 2 to 3 years would not be effective; they suggested doing them more frequently. There was no difference for the group between collecting the environmental samples themselves and having the staff from the study doing it. Mailing the sample was accepted if postage was paid by the study.

When asked about completing a twenty-minute survey, they all agreed. They would answer a paper questionnaire or in person at the doctor's office, but not over the phone because they don't have the privacy and most of the time the phone line belongs to someone else in the household. They would not use the Internet to answer the survey either because they lack access.

When asked about blood and urine sample collection, the participants would agree to provide a urine sample, but they would not provide blood sample. They were very skeptical about the use of the blood. They mentioned that they didn't feel that they can trust “them,” referring to the study staff. One participant said: “no blood, I don't trust them; there are so many things that can be done with it.” Another participant said that her participation will depend on the legitimacy and the purpose of the study.

The group was asked how they felt about letting the doctor examine the placenta after birth and all the participants agreed except for one. She said that more information should be provided by their doctors about what would be learned from the tests. The other participants continued referring to the examination as an “experiment” and said that currently placentas are being examined when the baby died during labor, or when abortions are performed. They also thought that placentas are currently being thrown away or experimented with it, so they would never find out if the tests were done without their consent. Only one participant mentioned that information regarding illness could be found in the placenta.

The group agreed to provide the umbilical cord and blood for testing but they also wanted to learn more about it. The group mentioned hearing about stem cell research and storing the information for their future health benefits.

All of the participants agreed to provide a breast milk sample.

When asked about their willingness to provide a “meconium” sample, the participants were surprised and confused. One participant thought that would involve collecting the first sample from the womb and after birth she would consider the baby’s second bowel movement. Others said that it was “weird!” When asked to allow for urine and blood samples to be taken from the child, they said it would depend on the purpose and how much sample would be collected. They did mention that any sample collection would have to be done during regular doctor’s visits.

The group was very reluctant about providing fingernail clippings and hair samples. The hair sample was more an issue for them because of the fear of DNA information being provided to the authorities.

- “What for? Some are doing DNA [tests] with hair, this is too far, too much.”
- “No- I don’t care what it is for – I would protect my child all the way – I don’t want my child to be identified in the future if the police have access to it. It’s concerning that somebody may have access to all this information. My child may be upset when he/she grows up because all this information is out there.”

The group would not provide baby teeth because it’s considered a “precious memory.” They would not provide buccal cells either. One teen considered this to be an invasion of privacy and she stated that this is already happening but the public doesn’t know about it.

When asked whether they would agree to genetic testing, the group also had a negative reaction. The group believed that their doctor has the genetic information for them and their doctor would have it for the child as well. They expressed concerns that they were being lied to about the purpose of the study. In the event they would agree to genetic testing, they would like to have all the information even if it can not be interpreted at that time.

There was no consensus among the group regarding the age for the child to start signing the consent to participate in the study on their own. The ages suggested were: 14, 15, 16 and 18 years old. One participant said: “whenever you become a more mature person. If the teen is a mom, she should be able to make the decision on her own because she has an adult life and a baby.”

When asked about if they were enrolled in the study as a child, would they consent for their child to be enrolled in the study, the group had a mixed response.

- “It depends of the benefits for the child.”
- “Generational? I am not sure about it – going from generation to generation it is not a good idea.”

- “If the child has disabilities and it is not able to do it, the parent would have to continue making the decision.”

Part 3: How Do We Keep You Interested?

The questions about whether gifts were appropriate in return for participation led to a group discussion on the needs of teen moms. They mentioned that most teen moms do live in “someone else’s place” and one healthy way to raise a child would be in their own place. However, they recognized that having their own place would resolve only part of the problem because they will need basic living items to furnish the apartment or house. The participants suggested providing teen moms enrolled in the study with Section A housing or rent vouchers so that they can live on their own. The group also mentioned that access to day care is extremely important to raise a healthy child and also for teen moms too because that would allow them to go back to school or to work. The group mentioned gifts such as school tuition, scholarship and US bonds, but their main concern was how to improve their living conditions today.

The participants were not interested in having Internet, web TV and cable services. The group also did not view the results of the study as an incentive; they considered receiving the results of tests as a condition of participation. The group would not make charity donations because they considered their needs greater than others.

Regarding money for participation, the group suggested that participants (mom and/or child) should get paid every time they are contacted and for every sample they consent to give. The amounts suggested were: biological samples \$200 or \$300 each. One participant suggested paying yearly for the “package,” this would include the biological samples, doctor’s visits, environmental samples, and the survey – the amount would be \$1,000 (one thousand dollars). The group wanted to receive the monetary incentive in addition to gifts “that would be meaningful and appropriate for the child for being enrolled for 21 years in the study.” Only one participant suggested lowering the incentive because participation in the study would be a worthwhile activity.

- “I don’t think we should get that much because this is a good thing to do.”

None of the participants said that they would feel obligated to participate if they received gifts and/or incentives from the study.

If the teens agreed to participate in the NCS, they would like to stay informed by receiving a newsletter or updates through the mail. The group agreed that personal information such as test results should be sent by certified mail or courier. The group would participate in local meetings too if the time were convenient for them.

The participants would like to receive all the information concerning the child and the study results as soon as they are available. Regarding the frequency of these updates, they wanted to receive them after any contact made such as tests, doctor’s visits, or home visits. One participant mentioned that she wanted to receive demographics of the recruitment and enrollment process; she was basically concerned with having equal representation from all races and economic sectors of the population.

Part 4: Barriers to Participation

Throughout the evening the group expressed a high level of mistrust of the government activities and government research. The group also thought that the NCS and other similar studies primarily target the poor and minorities. The participants made statements such as “They [the government] are never around helping the kids in the community; with the government you only hear about negative things.”

When asked what would help to ease their concerns and motivate them to participate – one teen responded that having a relationship with the doctor might make it more comfortable to participate. They agreed that they would like to receive the information from a reliable source, a doctor, the school or church. The group also suggested that the study provide more detailed information about what will happen with the samples and what can be learned from them. The group would also like to be informed about other similar studies that were conducted in the past or are planned for the future.

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3.3 Couples Trying to Conceive Focus Group Demographics

Demographic Characteristic	Chicago Female N=1	Chicago Male N=1	RTP Female N=4	RTP Male N=4
Age				
18-25	0	0	1	1
26-35	1	1	2	1
36-40	0	0	0	1
41 or older	0	0	1	1
Number of Children				
None	1	1	3	3
1-2 children	0	0	1	1
3-4 children	0	0	0	0
5 or more children	0	0	0	0
Ages of Children				
Less than 1 year old	0	0	0	0
1-2 years old	0	0	1	1
3-5 years old	0	0	0	0
6-11 years old	0	0	0	0
12 or more years old	0	0	0	0
Hispanic origin or descent				
Yes	0	0	0	0
No	1	1	4	4
Race				
American Indian or Alaskan Native	0	0	0	0
Asian	0	0	0	0
African-American or non-African-American Black	1	1	4	4
Native Hawaiian or Other Pacific Islander	0	0	0	0
White	0	0	0	0
Highest Grade or Year of School Completed				
Less than high school	0	0	0	0
High school graduate	0	1	1	2
Some college	1	0	2	1
College graduate	0	0	1	1
Graduate school	0	0	0	0
Total Annual Household Income				
\$10,000 or less	0	0	0	0
\$10,001 to \$30,000	0	0	1	1
\$30,001 to \$50,000	1	1	0	0
\$50,001 to \$75,000	0	0	2	2
\$75,001 to \$100,000	0	0	1	1
More than \$100,000	0	0	0	0
Area of Residence				
Urban	1	1	3	3
Suburban	0	0	0	0
Rural	0	0	1	1

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3.3.1 Couples Focus Group Summary (Chicago)

This group was held in Chicago offices of RTI in December 2003. Five couples were recruited but only one couple attended. Three of the couples called to cancel the evening the group was scheduled and one couple did not show up at the facility at the appointed date and time. Both members of the couple were between 26 and 35 years old. The female partner reported having had some college education; the male partner graduated from high school. The couple's annual household income was between \$30,001 and \$50,000.

Part 1: How Do We Get You Interested?

The couple thought that the doctor's office – specifically the gynecologist's office—would be a good place to learn about the study. The male partner also suggested TV commercials. Neither thought that posters on public transportation would be helpful.

- “No posters in public transportation because we see so much that we really don't pay attention.”

The couple agreed that they would want to know the background, history and purpose of the study before they would approach researchers about participation. They would like to know about the credentials of the people working on the study and whether they are qualified enough for me to trust them. They would also want to know how long the research organizations have been around.

- “I think people tend to pay attention when they see a name they know...a good well respected organization is a good idea.”

The couple also wanted to be sure that there was no way that they could get “locked into” something that they later wanted out of. The female partner expressed two additional concerns. She wanted to know if it would cost anything to participate or if participation would profit her or her family. She was also concerned about whether there would be “any penalties for anything that we might say.” She elaborated that sometimes the family says or does something that they do not feel is harmful, but may be interpreted differently by others or may “offend someone else.” The concern stemmed from things the children might say. The male partner also made a comment about convenience:

- “I understand that everything can't be too convenient but you don't want to be too inconvenienced about time and location”

When asked how they would feel about participating in the NCS the couple said that being part of a national study would give them an insight into how other families and children are growing in different parts of the country. They also felt that it would give them the opportunity to speak on behalf of other people around the state and the country. They noted that neighborhoods differ like “salt and pepper” and they would welcome the chance to help communicate how people live and grow up in their community. The participants said that knowing somebody else who is participating would add more confidence to the overall process for them.

In their opinion having a celebrity as a spoke person would not be important. However, it would be important to have a medical expert as spokesperson, someone optimistic and who cares about finding cures – which will motivate and convince others to participate.

- “Someone who shares my ambitions and caring for the cause”

The single most important thing they would want to get out of participating in the NCS would be to learn about their own fertility and the health of their child. They also felt it would be important to contribute to science and “bring alert [sic] to my community so people become more educated about water systems and ways to reduce risks.”

Prior to discussing the activities, the couple offered that they would be very interested in knowing about all of the data collection and the purpose for it.

Part 2: What About the Time Commitment and Data Collection Activities?

The male partner was concerned that there were not enough visits to adequately get to know the study staff and for the staff to get to know them. They expressed some concern about how informative the data collected once a year would be. The couple also focused on convenience and suggested collecting biospecimens during routine doctor’s visits.

- “Maybe there should be a few more doctors visits because you can’t get too far if you meet once in a blue moon.”

The couple thought that it might be difficult to get the children to cooperate once they reach age 13 or 14. They suggested that the study offer the children some type of “reward or activity, not necessarily monetary, but something challenging like a game” to get them to look forward to the visits. Also, the couple felt that transportation should be provided.

Regarding the environmental sample collection, the couple wanted to know in advance the purpose of the sample collection, what was involved and who would perform the collection. They indicated that the person should have an ID displayed at all times to ensure legitimacy. They thought once a year would be fine.

The main concern about the activities was convenience but they were also concerned about privacy. The couple would be willing to participate in all of the activities if “they are at my convenience,” but asked how personal the questions would be. They noted that there might be some personal information that they would not be willing to share with anyone. The female partner preferred to be surveyed by mail, especially if asking for personal information. She would like to complete the survey at home and bring it to the doctor’s office with her. She definitely did not want to be interviewed over the telephone saying that she would get distracted. The male partner thought it best to complete the survey or be interviewed during the office visit—primarily for convenience, “to knock it off all at once.” However, he qualified this statement by saying that being interviewed at the office would be acceptable for collecting general information but for personal information, he would prefer a paper survey. Both

partners felt that the Internet was an acceptable mode of data collection for general information but not personal information.

The couple was willing to provide most if not all samples if they were fully informed of the purpose of the collection and what they would learn from it. They would want to be fully informed at the beginning of the study about what would be involved and why. The male partner said that he would be willing to provide a sperm sample (the female asked where he would have to go to collect the sample). They were also willing to chart sexual behavior and menstrual cycles and stated that they were attending a fertility clinic and had to do those things anyway. Both were willing to give blood and urine. The female partner indicated that she would provide a breast milk sample if she could collect it at home without anyone "waiting or watching."

The couple was very interested in the collection of placenta and cord blood noting that they had read about stem cell research and wanted to store stem cells for the future of their child. They added that they would provide the samples if they could also be stored for their own future use if it should ever become necessary.

The couple was a bit confused about the meconium sample noting that it could be collected if "it didn't hurt the baby." When asked how they felt about the child providing urine and blood, they indicated that urine was fine but they wanted to minimize the number of times the child gets "stuck" for blood. They suggested collecting blood all at once for a number of purposes.

- "A hollerin' child after a shot is not nice."

The male partner confused the blood draw with getting a shot and noted that shots sometimes cause children to develop fevers.

The couple thought that collecting buccal cells and fingernail clippings would be fine as long as they could perform this collection at home "when the child was asleep." They would also provide baby teeth. They were concerned about the hair and agreed to provide only "dead hair" taken from a brush or comb.

The couple would agree to genetic testing as long as it was "not painful to the parent or child." Their main concern for this testing was confidentiality and that their information would not be released to anyone, at least without being informed that the information would be released.

The couple also expected to receive all information and test results so that they could keep a file as "documentation of the whole process and a record of the collection over the years." The male partner expressed the desire to have "his own personal file" of the information being collected through the years so that he would have the same information as the research team. He indicated that if there ever were a conflict, it would be easy to resolve if he had a complete record of their participation and results. The couple felt that it was important to participate in the study because they said: "Today I might not be able to help someone, but tomorrow by being a participant of the study."

In terms of the age at which a child can consent, the couple agreed that at age 14 or 15 children become their “own individuals; not grown individuals” and that they should have a say in participation. When asked if they should be able to sign their own consent forms, the couple indicated that that would depend on the child’s maturity noting that some children “deal with responsibility better than others.” The couple agreed that parents should motivate the child to participate, but not force them to do so.

Part 3: How Do We Keep You Interested?

The couple liked the idea of coupons and gift certificates for infant supplies, school supplies, child photos, toys and children clothing up to age 13. They would like the child to receive some type of scholarship for college tuition or living expenses during college. The amount would depend on the financial situation of the child but with limits. The couple liked the idea of receiving Internet, Web-TV and cable services since they are already using them and would welcome relief from paying for these services. They did note that these services should also include routine maintenance and repairs.

The couple did not view the results of the study as an incentive; they considered that receiving the results was a given. They reiterated their desire to receive the data/results and suggested that getting the results in a summary form on a yearly basis would allow them to take a look at their lives and make changes where necessary.

The couple also noted that receiving the results from the environmental testing would be very important because they would like to know more about their local environment and if there are any risks associated with living there. The couple said that the results would help them to make decisions that would help them to improve their situation

The couple would perceive a donation to a charity “as an important part” of an overall incentive package. They noted that “you’re doing something to help mankind – so why not help another cause.” The couple also felt that coverage of medical expenses would be a good incentive, “not only for the testing or to collect samples for the study, but for all the child’s medical needs.” The couple did not feel that decreasing the number of samples collected should reduce the amount or type of incentives. Again, they thought more data was better and did not want to compromise the data.

In addition to receiving gifts the couple thought monetary incentives would be good—“who can’t use money!” They recommended that all travel and transportation be covered and initially suggested \$100 per doctor’s visit. They noted that \$100 can “help anyone to cover a bill.” Upon further thinking the couple suggested \$30 for a survey and \$50 to \$75 for an office visit. They also recommended a gift certificate for home supplies for environmental samples. Suggested stores included Target, Wal-Mart, and a local grocery store.

They did not consider any of the gifts on the lists or money to be coercive. They felt that the list held something for a wide “spectrum of people.” The male partner indicated that sometimes the difference between participating and not participating could be a small incentive that shows that the study appreciates the time participants take to be involved with the study. However, if the incentive was too

large, for example \$10,000, the female partner indicated that she would be suspicious “I wouldn’t believe that we would ever get it.”

If the couple participated in the NCS, they would like to have the option of receiving information over the Internet. They would like to be able to check their schedule. They suggested the study send an email message with a web link. The male partner would like to receive reminder postcards about the study activities. They would attend a local meeting— depending on the topic- and only if attendance was totally “voluntary.” They would like to receive breaking news whenever it happens.

The female partner suggested that to keep people engaged between visits, the study should send out newsletters or notices with a distinctive logo and some type of coupons or some small item like pens or magnets to keep the study on people’s minds. They would like more detailed information twice a year including study findings.

As they said earlier, they would like to receive all the information pertaining to them and to the study “everything would be more helpful than harmful.” This includes information that cannot be clinically interpreted at the time.

- “Yes, because you never know – it could become more publicized down the road and you could be like my child was diagnosed with this a few years ago and nobody knew what it was. It will give you an idea that something did come around in later years.”

Part 4: Barriers to Participation

The couple said that anything that doesn’t reflect a good public image, any negativity surrounding the doctors or administrative staff, or any negative media reports “would make me second guess what I am doing.” The couple indicated that they would not participate or would quit the study if they had to deal with rude or impersonal staff. They said that they would not want to feel “like a unit of an experiment.”

Another major concern was having the family’s personal and health information misplaced or released without their consent. The female partner was concerned that the study has “legitimacy.” The couple thought it would be easier and more appealing for them to have their own doctor participating in the study in case there is something they don’t understand or something needs clarification.

They would like to see that the study is sponsored by a “large government agency” (“like the FDA or something”) and that it has “a seal of approval.” They would like to see an actual government seal on the documents. They would also want penalties for misuse of the data or those who violate a participant’s confidentiality and privacy.

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3.3.2 Couples Focus Group Summary (RTP)

This group was held in the RTP offices of RTI in November 2003. Five couples were recruited; four couples attended the session. All eight group members were African-American. One woman was between 18 and 25 years of age, two women were between 26 and 35 and one woman was age 41 or over. One of the men was between 18 and 25 years of age, one man was between 26 and 35 years, one man was between 36 and 40 and one man was age 41 or older. One of the women and two of the men had completed high school; two women and one man had some college; and one of the women and one man completed a college degree. One couple reported annual income between \$10,001 and \$30,000; two couples reported an annual income of between \$50,001 and 75,000; and one couple reported an annual income between \$75,001 and \$100,000. Three couples lived in an urban area and one couple lived in a rural area.

Part 1: How Do We Get You Interested?

The group members suggested that the grocery store, bank, social services offices, churches, doctor's offices, clinics, and hospitals would be good places to hear about the NCS. The group also thought a lot of people could be reached through the life and classified sections of the newspaper, posters on public transportation, public service announcements on television, and billboards. They also thought that information such as pamphlets, posters, and newsletters from healthcare providers or insurance companies would also be a good means of hearing about the study.

The kind of information the couples would like to know about the NCS before they would make contact with study staff included, "What they are looking for... what is the purpose of the study, what's the goals of it?" Several individuals stated they would want to know "Any agreements you have to sign." The other kinds of information the couples would want to know would include the study sponsor; the credentials of the researchers; where the study would be located and how long it would last. The group would also want to know about how their privacy would be protected, how the results would be used and how the participants would be compensated.

One group member noted that the benefits of the study for the children is what would most interest him in participating, "What reaction the kids are going to have when they are initiated into the program. Basically, what is it going to give them?" All agreed that it would be exciting to be part of a large national study and one man claimed that doing so would give you "bragging rights." One woman asked if the results would ever be publicized and seemed interested in the public benefiting from the information. The group agreed that a well known doctor, such as the Surgeon General, would be a good spokesperson for the study and it should definitely be "somebody people would listen to." Several women suggested that Oprah Winfrey would be a good spokesperson.

The entire group agreed that the single most important thing they would want to see come of their participation in the NCS would be "to make sure that my family participation is really helping somebody." One woman stated that she would want the researchers to tell her what has been learned and how it relates to her everyday life.

Part 2: What About the Time Commitment and Data Collection Activities?

The group members were most concerned over who would be paying for the doctor's visits when asked whether they thought they could maintain the level of participation.

- “Who's paying for those visits?”

Five group members also voiced that “That's a long time.” The group agreed that requiring individuals to pay for the visits would hinder participation but maintaining this level of participation would be no problem if all visits were paid for by the study, partially because children already have to make frequent visits to the doctor. The group agreed, “It wouldn't be bad but it's just keeping people interested and making sure they're doing it.” Several group members suggested that it would be difficult to keep kids involved as they get older because they will want their independence. Several group members seemed surprised and shocked that “They come to your house to collect water and dust?” All agreed that having transportation provided or a mobile lab would encourage participation.

All group members agreed that the initial activities would not be a problem because, “You have to do that when you go to the doctor right now, that's just general information that is required now by doctors.” Several members noted that the privacy of the information would be important. The group members reinforced that cost would be an issue but if there were no costs associated with the visits, there should be no problem.

All group members agreed that sexual activity diaries or menstrual cycle charting would not be a problem. One male group member vividly responded with a “WHOA, what do you mean, they're going to have to document like every time they...?” Several group members discussed that if you are having a hard time trying to conceive then you have to track that stuff anyway. When asked about the questionnaire, the group unanimously agreed with one man's statement, “I would prefer to do it while I am there, that if you have any questions the person is there for you to ask them.”

Seven group members agreed that they would rather have someone come to their home to collect tap water or house dust rather than doing it themselves, “I would rather have them come to make sure they get exactly what they need, that way I can't mess it up.” However, all agreed that if they had proper instruction they would be willing to use the kit. One male member stated a strong preference for collecting the sample himself over having someone come to his home. One woman was very interested in why the researchers would want these samples, “Why would they do that, what is that for?” Another group member responded that “these tests would be for your own protection and could tell you if you have molds, asbestos, or chemicals in your water.”

All group members would have no problem with completing a 20-minute questionnaire once or twice a year. The group agreed it would be nice to have an option between telephone, mail, and Internet response.

All male partners agreed that they would have no problem with providing a sperm sample. One male stated, "If I am there in the privacy of my home," invoking laughter from the group. Another member asked, "Why would you need a sperm sample?"

Six group members would agree to have a blood sample drawn, but two males said they would refuse to have their blood drawn. The entire group would agree to the collection of urine samples.

The females unanimously agreed that they would have no problem with providing urine and blood samples while pregnant stating, "Don't they do that anyway?" The females would be more comfortable if they were reassured that the healthcare provider knows what they are doing and that they "use the smallest needle."

The group seemed to be equally split on whether they would let the doctor send the placenta to the laboratory for some tests. One woman responded that she would have no problem with that. Another woman stated, "I don't know about giving that...that's very personal...it's like a part of you." Several of the members thought the idea was "gross" and they didn't want someone testing their placenta.

All group members agreed they would be willing to let the doctor or nurse collect a sample of umbilical cord blood for testing. One group member stated that "they are doing that a lot now and there are more research studies and a lot of good comes from it." The group agreed that it helps babies. One group member asked, "What's the difference between cord blood and regular blood?"

All women agreed they would have no problem providing a small sample of breast milk. One woman stated, "We have women at the bathroom at work doing it...pumping their breast." All agreed it would be easier if a pump was provided. The group wondered if the results would be provided to them if there was something wrong.

The entire group had no problem with having a nurse or technician collect samples of hair and fingernail clippings from their child. The group unanimously agreed that they would rather have these samples collected at the doctor's office.

All group members would agree to have a nurse or technician collect buccal cells from their child because, "It's not going to hurt." The group members agreed they would be more likely to provide these samples if they knew what the samples were being used for and that they "would be notified if they found something wrong."

All the couples would agree to provide one or two of their child's baby teeth for testing stating that when they lose the teeth they are just thrown away. The group agreed that they would be more comfortable with providing the teeth if they knew what type of information would be gathered.

The entire group agreed that genetic testing of their child would be fine as part of the study. All members would want to know the results of the testing in order to help their child. All participants agreed they would not participate if they were not able to know the results. One female stated that it would be

nice for each couple to receive a personal profile with test results. Many individuals expressed fear and apprehension of knowing the results, but stated that disclosure was best.

The group unanimously agreed that their child should be able to consent for him/herself no younger than 18 years of age or upon graduation from high school.

Part 3: How Do We Keep You Interested?

The group agreed with one member's statement about the importance of the child's health information.

- "I think would be the number one gift...knowing step by step what is going on with the child."
- "Oh man, that's the number one right there."
- "That's something that could actually benefit the child for being in the program."

It is interesting to note that the male partners dominated the conversation regarding incentives. The group members liked the idea of coupons, gift certificates, charity donations, and money. Everyone agreed that if they knew they would be compensated a small amount for each visit, would definitely be an incentive to stay in the study. The group agreed the money could be used for various things such as fertility drugs and testing for those trying to conceive. The group agreed that incentives would need to vary based upon socio-economic status and that having options would be best.

The group agreed that incentives would be appropriate for biologic samples and agreed that money would be the best option:

- "I think monetary [incentives] will probably get them [to participate]."

The group agreed that cash equivalents such as gift cards, utility credits, gas cards, or grocery coupons would be almost as effective and agreed that desired incentives are "going to be different for each class of people." Once again, the group reinforced that information about the health of the child is the most important and several doubted if they would participate if unable to know the results of tests. One man stated that "knowledge is power" and no amount of money would override the despair of having his child die from a disease that could have been prevented or treated had he known the results of testing. Several group members highlighted the fact that such a situation could have legal implications for the study. The group stated that the study should also offer incentives for people who cannot conceive such as offering information on adoption. Other incentives of interest to group members included electronic equipment, diapers, milk, and charity donations.

The entire group agreed that the study should offer money for participation and more specifically, college tuition. One member stated, "I think the most important thing for a child going through this thing is offering compensation for tuition." The group members thought that it would be fair to offer as much money as you can give but one man suggested the sum of \$1000 a year stating over 21 years that would be approximately half of his child's tuition. One male stated that he would not compensate at all until the

study was completely over. However, the majority of the group felt that participants would need to be compensated throughout the study to remain interested with a larger reward at the end.

All group members agreed that none of the incentives would make them feel as though they had to participate. One member rhetorically asked, "What would you do for a million dollars?" and stated that the incentives must be "worth your while."

The group stated they would like to stay informed with what was going on in the study through newsletters, websites, e-mail, yearly meeting, and support groups. One member suggested "Have a meeting once every year or two years" but was countered by another's response, "I don't know if I want to congregate with people from the study." The group agreed that the information would need to stand out from all other e-mail and mail and suggested that a phone call or letter may be a better mode of communication. The group also liked the idea of having hotline or password-protected website.

The group agreed they would like to receive information monthly or quarterly, in addition to the information received after each doctor's visit.

All group members would like to see the recent and ongoing findings of the study within the regular updates. Several individuals were interested in receiving information summarized by age group, frequency, and region in the updates. The group members were also interested in information about how many and what types of individuals are participating in the study. The group members would be interested in receiving a referral fee for referring someone into the study. One individual suggested that the study should offer an internship as an incentive in which the 18-21 year old participants would recruit new participants.

The entire group agreed that there was no information they would not like to receive, but would like all information they receive to be in non-technical terms. Although they would want to know "everything", two women stated they would be "worried as hell" if they were told something was wrong with their child but the study didn't know exactly what it is. The group members agreed that they would not want to participate in the study "If they were not willing to disclose information." The group members agreed that despite any amount of payment they would need to know the health information of their child.

Part 4: Barriers to Participation

The group members had several concerns about participating in a large national children's health study. Several group members were concerned about the healthcare providers and that they "would want to know that you have the credibility and credentials to be able to do this job. The group agreed that the healthcare staff would need to be trained, certified, credible, and trustworthy. The group members had several questions/concerns about the privacy and protection of their healthcare information and samples.

- "How long are you going to hold the samples?"

- “If you gave a sperm sample you would want to be sure it was not cloned or given to someone to become pregnant.”

Several group members mentioned concern about the potential for misuse of their genetic material in criminal trials and concern about signing away their rights. Several group members wanted to be assured of legal protection from prosecution. One group member asked, “Is this still going to be classified as my property or theirs?” Several group members seemed to think that you sign over all your rights when you sign a consent form although one man stated you “could probably” stop participating at any point because it is voluntary.

The group members agreed their concerns could be addressed by the study in a number of ways. The members’ concern over credentials could be overcome by demonstrating the training of healthcare professionals or being allowed to change or choose doctors at will. The concern over the duration of the study would be relieved by renewing consent each year and reviewing the year’s upcoming requirements. HIPAA protections and educating participants on the storage and disposal of their samples could alleviate privacy concerns. It is also important to group members that the incentives are handled with honesty and that there are no tax consequences. Once again, the group expressed that they want full disclosure of information and would like to be referred to additional resources for more information.

3.4 Biological Specimen Group Demographic Characteristics

Demographic Characteristic	Chicago N=8	RTP N=7
Age		
18-25	1	0
26-35	5	4
36-40	0	1
41 or older	1	1
Missing	1	1
Pregnant		
Yes	2	1
No	5	5
Missing	1	1
Number of Children		
1-2 children	0	3
3-4 children	0	1
5 or more children	0	1
Missing	8	2
Ages of Children*		
Less than 3 years old	2	2
3-5 years old	2	3
6-11 years old	4	4
Missing	1	1
Hispanic origin or descent		
Yes	1	0
No	6	6
Missing	1	1
Race		
American Indian or Alaskan Native	0	0
Asian	0	0
African-American or non-African-American Black	6	0
Native Hawaiian or Pacific Islander	0	0
White	1	6
Missing	1	1
Highest Grade or Year of School Completed		
Less than high school	1	0
High school graduate	2	1
Some college	3	3
College graduate	0	0
Graduate school	1	2
Missing	1	1
Total Annual Household Income		
\$10,000 or less	0	0
\$10,001 to \$30,000	3	0
\$30,001 to \$50,000	3	1
\$50,001 to \$75,000	0	2
\$75,001 to \$100,000	1	1
More than \$100,000	0	0
Don't know	0	2
Refused	0	1
Missing	1	0
Area of Residence		
Urban	5	
Suburban	2	1
Rural	0	4
Missing	1	2

* Some women had children in more than one age group.

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3.4.1 Biospecimen Focus Group Summary (Chicago)

This group was conducted in the Chicago offices of RTI in November 2003. Eleven participants were recruited and eight attended the session. The majority of the group was African-American and two of the women were currently pregnant. The group was quite diverse with respect to education and, with the exception of one participant who reported an annual income of over \$75,000, all reported annual incomes between \$10,000 and \$50,000.

Part 1: Orientation to the Study

After hearing a brief overview of the NCS, the women were asked what they thought would most interest their families in participating. The group mentioned that they would want to learn more about what causes asthma, allergies and childhood diabetes.

- “Why they need to take insulin at school.”

The women expressed some concern that this type of study is usually done after something has happened in the environment. They were also concerned about the level of commitment and who would be invited to participate.

- “Takes 21 years to get results—it’s a big commitment—would need an incentive.”
- “Are the medical tests in addition to the regular doctor visits?”
- “Would this be broad-based or only for children in government programs—they’re the ones who seem to get all of these diseases.”

The group indicated that they would want to know more about the risk factors—small or large—before contacting the study. They would also want to know how their privacy would be protected and what the government planned to do with the results. There was real concern about the information “hurting” in the future.

- “What would they do with the results? Would they keep them or share the information?”
- “Where would it be stored?”
- “You don’t know if it will hurt you down the line; you don’t know how it might affect you later.”

Most of the participants were working parents who were concerned about the schedule and whether the children would have to be taken out of school for visits. One woman suggested that if organizations sponsor the study they should have a “good reputation” and be known to be “fair” and to work in the “public interest.”

Part 2: What About the Time Commitment and Data Collection Activities?

After reading the list of activities, one woman said that she would not participate in the NCS. Although she indicated that she did not move frequently, she was concerned that the study would have a hard time following people for 21 years when they do move.

- “How would you keep up with the families?”
- “Might as well have a Lo-Jack on the child.”

The group indicated that the number of visits would be too many unless the visits could be combined with well-child visits. The group also wanted to know what incentives would be offered for such a long commitment.

- “Twenty-one years-might as well be a distant relative.”

One woman indicated that the study should address the entire environment not just the household noting that we know bus fumes are harmful “we don’t need 100,000 kids to learn about that.”

- “I thought the study would take into account the entire environment not just house dust and tap water. What about soil samples and the water coming into the neighborhoods.”
- What about the schools; daycare?”

The group liked the idea of gradually reducing the number of visits as the children get older and they agreed that the one-hour length for the visit was acceptable.

- “Kids have more activities...”

The group thought that travel vouchers would be welcome to compensate for travel expenses to the visits.

The entire group agreed that they would be fine with someone coming to their home to collect tap water or house dust because they would want the samples collected properly. However, they did think that it would be convenient to use a kit, if was easy to use. One woman wanted testing for lead performed as well.

The women also agreed that it would be “no problem” to complete a 20-minute survey by mail or over the Internet.

The group would agree to provide blood and urine samples during pregnancy if the samples were taken from the specimens that they already were providing as part of their prenatal care. The group also noted that they would want to see their personal physician for all study-related activities.

All of the women would be willing to let the doctor send their placenta to the laboratory for some tests, as long as it did not interfere with any other tests that might be required and if they could receive the results.

The group would be willing to donate a sample of the umbilical cord blood for testing as long as there was enough cord blood to bank for the protection of their other children. One woman indicated that she would want the doctor to sign an “informed consent” document telling her exactly what was to be done with the blood.

- “Only with signed consent so we would know what is really going on.”

The women agreed to provide a breast milk sample and preferred to collect the sample at home using an electric pump. They agreed that a manual pump was difficult to use.

All participants agreed they would not object to allowing a nurse to collect a meconium sample as long as they are made aware of what tests are being performed.

- “They can have it for the next 2 years.”

When asked how they felt about collecting blood and urine from the infants and children the group wondered about how the urine would be collected. They were opposed to any type of catheterization. The group also thought that a finger stick would be fine but preferred “no needless pain.”

The group had a mixed reaction to the collection of fingernail clippings and hair. The biggest reaction to the fingernail clippings was the fear of cutting the child's fingers.

- “I would be concerned about someone clipping my kid's fingernails. One slip of the clipper and you've got a little piece of the pinky.”

At least half of the group had a strong objection to the hair samples. One woman said that in her family they do not cut the women's hair. The Hispanic woman suggested that hair is used in Voodoo rituals and therefore she would need to know exactly what was to be done with the hair sample. Other women objected because they babies don't have much hair for at least a year. These women would allow hair to be taken from the child's brush but they would not allow a clipping or a strand to be pulled.

The group agreed that they would be fine with having buccal cells collected from their children “as long as it doesn't hurt.” The women agreed that it would have to be done by a technician skilled with collecting the samples from children.

Participants varied on how they felt about the collection of baby teeth. One woman said that she keeps all of her children's teeth and would not provide one for testing. Another woman said that she would not give the first tooth but would give the second. Two of the women said that they would provide the teeth because they “just throw them out.” The other women said that they would need to know what the teeth are being tested for before agreeing to provide them.

At this point in the group, one woman said: “What don't they want? This is a lot.”

The group also varied in their opinions about genetic testing. One woman said that she has diabetes and her husband has asthma and to the extent that they could learn something about their family history, she would consent to testing. Another woman was less enthusiastic about agreeing to testing. She said that she would have to work with her provider and if he thought that there was something wrong, she would agree to the test. The only other way she would agree to the testing is if her provider indicated that it was a standard screen like the newborn screening.

The group was very suspicious and concerned about confidentiality. They wanted to know what the government would do with the results and were concerned that the results would hurt the child in the future. Most of the group agreed that assurance of confidentiality would help allay some of their concerns.

- “[Knowing the results] could prevent the child from getting insurance; prevent him from getting a job.”

The group also wanted to receive the results of testing and would not agree to the testing unless they did receive the results. One woman noted that she didn’t trust the government and didn’t want the government having test results that she didn’t have.

The participants disagreed about the age at which the child should be able to provide consent. One woman said that at age 11 children start to make their own decisions. Another woman suggested age 16. The remaining participants said that the children should not be able to consent until age 18. One woman noted that if the incentives were large—college tuition—then she would encourage the child to continue through age 21.

Part 3: How Do We Keep You Interested?

After reading the list of proposed incentives one woman noted that the list was not impressive—”Photo coupons-you can get those anywhere.” Another said that a gift certificate might be motivating. The group agreed that the information about health and children’s health was a right and not an incentive.

For teens the group recommended cash, clothing, music, concert tickets, event tickets, and Internet access. One woman said Internet access is cheap “throw in a computer.” A donation to charity would be okay if they could get the tax deduction.

The group recommended that the study get a corporate sponsor like Hasbro to provide incentives. However, if the study is paying for the incentives, then the group preferred to receive money. The group also agreed that both parent and child should receive an incentive.

The group thought it best to pay each time a visit or activity takes place. One woman suggested a token system where the kids get a token at each visit and can then turn them in for a gift. Another woman offered that her doctor gives the child a book at each visit which gives the child “something to look forward to.”

The group agreed that money was appropriate and preferred and should be paid at every visit. One woman said that she was in a study that paid \$50 a visit and “a few hundred after 4 years” but it wasn’t worth her time. They suggested \$100 per visit and a yearly bonus—”do all of the visits and get \$500 at the end of the year.” Another suggested \$75 per visit and \$500 at the end of the year.

- “It’s all about convenience.”

All the participants agreed that none of the incentives discussed would personally make them feel like they would have to participate.

All participants would like to receive regular updates on test results and both personal and community results. One woman was concerned that the local environment be tested as well—soil samples in the community, schools, and daycare settings.

The group decided that they would want their results but that they would want some type of “buffer” when hearing bad news. They would want to hear results of tests from their health care providers and they would like to have counseling if the results are negative in any way. They would want results of tests even if the results could not be interpreted.

- “If something would be emotionally shocking, I would want to be buffered.”
- “Bad news requires counseling and personal talks.”

Part 4: Barriers to Participation

The major concerns voiced were the collection of data about the community and the mistrust of the government. One woman who works for an attorney said that through her interactions at work she has become very wary of having anything to do with the government. Others were concerned that the government would find something wrong with their residence and make them move without providing a new place to live. One woman noted that she didn't trust the EPA—“The EPA is not protecting us now.” The same woman noted the “\$100,000 tax deduction” for owning an SUV as evidence that the government and the EPA are not to be trusted. By far the biggest concern seemed to be about confidentiality and privacy of personal data.

- “What if my child can't join the military because the government has data?”

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3.4.2 Biospecimen Focus Group Summary (RTP)

This biospecimen group was conducted in the Research Triangle Park offices of RTI in November 2003. Nine participants were recruited and seven attended. All seven women were white and most had completed at least some college. One of the participants was currently pregnant. The group was quite diverse with respect to education and income.

Part 1: Orientation to the Study

The group members agreed that being part of a national study would encourage their participation. All agreed that “A lot of times you don’t find out what is going on, so if you’re involved in it, you find out what is going on.” The group agreed that the purpose of the study and their knowledge of current problems with the environment would encourage their interest. One woman specifically stated that knowing the motive of the study would interest her.

- “Is there something already going on in the environment that is causing them to want to do this thing?”

Another woman suggested she would be interested in “being able to get to the bottom of things.” The group unanimously agreed that they are aware that something in the environment is causing problems with their children and they would definitely be interested in a study seeking the answers to these problems.

All of the group members would like to make sure that the researchers are independent of outside forces that may be manipulative or dishonest with them or others.

- “I wouldn’t have to worry about the research being tainted by the drug company or some outside factor, because I wouldn’t want to participate.”
- “I don’t want to be part of a study where they use me to lie.”

The group reinforced that it was very important that the researchers be totally honest with them and include them in everything. The entire group agreed that privacy, credibility, and confidentiality were all very important. One woman voiced concern over having her information displayed on the Internet. Another woman suggested that participants should be protected by HIPPA regulations so their children’s records would be protected and the insurance companies could not use the information against them in the future. They all agreed that safety was most important and that the study measures should be non-invasive, as they would not want their children to be “poked and prodded.” The entire group agreed that they would want to know all the participant requirements and who is sponsoring the study before agreeing to participate.

Part 2: What About the Time Commitment and Data Collection Activities?

All group members agreed that with yearly reminders they would have no problems with participating until their child was 21 years old. One participant shared that she had participated in a three-year study with yearly visits with no problem. Three women suggested the need for access to participating doctors in all areas of the United States, so that participants would not have to discontinue

participation if they moved. All women agreed that they would have very little parental control over their children's participation once they turned 18 years of age. Two participants suggested that if this age group were attending college away from home, providing transportation might encourage participation.

All women agreed that "piggy-backing" study office visits with normal doctor visits would be excellent as well as offering home visits, citing that this would relieve some parental work restraints and prevent contributing to the children's fear of doctors. Although the women agreed they should be given an option between home and office visits, because people would have different preferences. The women all agreed that the study doctors should be very knowledgeable about children and pregnant women (pediatricians or OB-GYN) and the doctor should be able answer any personal questions they may have about their child's health.

The entire group agreed that they would be fine with someone coming to their home to collect tap water or house dust, but would definitely want the results.

- "If that can be my water test for the year and I don't have to go out and buy it, I would be happy about that because it saves me money."
- "If I have E.Coli in my water, I would want to know immediately and would not want to wait for the results to be released."

All of the women would be willing to collect samples to send them in if they were given kits, although one lady was concerned that self-administered samples would not be as accurate. The group was split on whether they would prefer to send in a sample themselves or have someone come to their home to collect it.

Each member of the group agreed that it would not be burdensome to complete a 20-minute questionnaire although they expressed that they would like a choice between all modes (telephone, mail, and Internet). Several women agreed that anything sent through the mail should be easily recognizable in its packaging from other "junk mail" and surveys.

The entire group would agree to the collection of blood and urine samples. The majority of the group said that they would be more comfortable seeing their personal physician. One woman stated that people already see so many doctors, that one more wouldn't make a difference. Another woman said she would rather see a doctor other than her own personal physician and "keep it separate" because her doctor already thinks she does "weird things." All the women agreed they would not want to be forced to choose their obstetrician based on a list of doctors available to the study.

All of the women agreed that they would be willing to let the doctor send their placenta to the laboratory for some tests, as long as it did not interfere with their ability to make "cord blood donations." Several women stated that they would not agree to donate their placenta to the study if this was the case. One woman stated she didn't know what happened to her placenta so she didn't care.

The entire group would be willing to donate a sample of the umbilical cord blood for testing. One woman voiced that if she had to choose between donating the cord blood to help a sick child or donate to the study, she would definitely choose to help the child. One lady who had a home-birth stated that this was fine as long as she had a method of sending the sample to the study, suggesting that the sample could be collected by a mid-wife or a study representative sent to her home.

The women agreed that their feelings about providing a sample of breast milk would be dependent upon whether they were nursing or not and were able to provide the sample. They all agreed that if the study provided a breast pump that would not only make providing the sample easier, but would also be an incentive or “enticement” to participate in the study.

All seven participants agreed they would not object to allowing a nurse to collect a meconium sample.

- “They can have the diaper and all the ones after it.”

The entire group would agree to the collection of normal blood and urine samples, as long as it was “piggy-backed” with the other study visits, because children do not like having blood drawn or urinating in a cup. None of the members would be in favor of having their child catheterized or have a “bag urine collection.” One woman asked, “Would you have to produce blood and urine for all four visits?” Another woman stated that it would be fine if it were only once a year but four times a year would be too much. All the women agreed that it needed to be as painless for the child and mother as possible.

- “I’m the Mom who couldn’t take them getting shots and my six year old still fears the needle...”

The women also agreed that the phlebotomist should be very knowledgeable. One woman stated that it should be someone who knows about the “magic patch” and how to take blood from children.

Several group members suggested that it would be easiest if they could either mail in the samples of hair and fingernail clippings or have them taken during other doctor visits required by the study. One woman said this would be difficult because her child has no fingernails. Another woman asked, “What about special needs children?” Several women with children who have special needs stated that collecting these samples from such children would be even more difficult.

The group agreed that they would be fine with having buccal cells collected from their children. One woman stated that she would rather not have to collect this herself and would prefer having this done by the doctor. Another woman agreed, saying that “If you are already in the doctor’s office for all these other things, they should go ahead and do that too.”

One woman disagreed by saying that she tried to stay away from doctor’s offices as much as possible. All members agreed that it would be nice to have an option as to whether to send in the sample herself or have it collected by the doctor.

The group unanimously agreed that they would probably not give them their child's first tooth, but providing one of them for testing would be fine.

All group members agreed that they would be fine with having their child undergo genetic testing as long as blood that was already collected was used to conduct the test and that they would have access to the test results. The group stated once again that HIPPA protections were very important.

The group members agreed that they would not participate if they did not receive the results.

- “Knowing the test results is a right for us, they should not keep our lab tests from us.”

The group raised the issue of whether changes that are made in the personal environmental changes based on research findings would taint the results of the study. However, one woman proposed that providing the genetic test results to parents would not taint research findings because genetics is an unchangeable attribute.

All participants agreed that it would be appropriate for their child to sign the consent form for him/herself at age 18, but no earlier.

Part 3: How Do We Keep You Interested?

After reading the list of proposed incentives one woman said that she liked the information about health and children's health, but that was a right and not an incentive. The group agreed that participants should receive options in the type of incentives they choose from. One lady shared that the only incentives on the list that would encourage her to participate would be information and donation to a charity. The group agreed that the incentives should be age appropriate and that coupons and gift certificates for stores such as Toys R Us, Zany Brainy, Wal-Mart, and Crazy Clothes would be nice. The entire group agreed that college funds would be an incentive to parents, but not to the children.

The participants agreed that both the child and parent should receive an incentive. The group agreed that, “You can't have incentive for the children that parents are going to disapprove of” thus agreeing that coupons and gift certificates were more appropriate than some of the other incentives, such as cable television. The group suggested that another alternative would be to allow parents to pre-screen the incentives before allowing their children to choose. One woman stated that it would be tempting to take away the incentive as a punishment if the child misbehaved, but then they would not want to participate. The group suggested that children might like music, ice cream, pizza, Chuck E. Cheese, movies, Disney World, skating, or bowling.

All group members agreed that they would expect better compensation and incentives for more invasive or time-consuming tasks.

- “If we were going to do something where there is going to be pain or greater inconvenience involved, a much better incentive would be nice.”

- "I'll do an on-line survey if you give me five bucks...but if you're going to want me to take time off of work to take my kid to get a blood test then you're going to have to come up with a much greater incentive."
- "Pin pricks would be at least \$25."

All participants agreed that if the study visits also served as well-child visits, they would be excited if the study paid the cost of the visit, or co-pay.

- "If you were paying for my urinalysis every month I would be all about it."

The group agreed that participants should be given the option between money and other incentives and that it should be fair compensation for the task. All the participants agreed that none of the incentives discussed would personally make them feel like they would have to participate.

- "If my kid just wasn't interested in having her blood taken this particular day and I knew that it meant giving up the incentive this particular time, it wouldn't matter to me."

However the group discussed that individuals in financial need may feel obligated to participate. For example, the group cited that Internet access has a significant impact on one's way of life and would be hard to refuse for someone who could not otherwise afford it. The group agreed that things that could be "taken away" such as clothes or toys may make participants feel like they had no choice but to participate.

All participants would like to receive regular updates on current study findings, participation, and funding. All participants were very interested in being kept up-to-date on the trends that the study was finding so they could take immediate action to improve their child's health.

- "If they start seeing that households where they are using Windex...the kids eyesight are going quicker."

Several of the members expressed interest in being updated on any other studies that may be "spawned" from this one. The women were interested in knowing how their child compares to other children and how their region compares to the rest of the United States.

The group was divided over how much information they would like to receive. Many participants stated they would not want a lot of technical information. The group agreed that they would like to have access to a web-site where, "I would like to receive the bottom line and if I wanted more information I could get it." Two women expressed the desire to have the raw data available for them to interpret and draw conclusions on their own. This information should also be available through the mail for individuals who do not have Internet access. All of the participants would like to be informed of study outcomes before they are given to the public. The group members would be very interested in receiving reports for their individual child and their state of residence and suggested that this could come in the form of a quarterly statement.

Part 4: Barriers to Participation

The majority of the women agreed that there was nothing about the NCS that would discourage participation.

- “As long as it is non-invasive and piggy-backed on the naturally occurring things we have to do to keep a child well and immunized.”

All of the participants were excited to see a study of this nature.

- “If I were going to have another baby I would do it.”

The group members are all very wary of insurance companies and would want re-assurance that insurance companies would not have access to their results and could not use the data against them (to possibly refuse claims). The group also felt that no identifying information should be placed on the website.

All group members felt the website should be password-protected. One woman suggested that she would want to receive personal test results from her personal doctor rather than from a website. Once again, several women were adamant that insurance companies should not be allowed access to any of the information, because of concern over insurance companies refusing claims. One lady said she would like non-participants to be able to find out results from the study. Several group members suggested and were supportive of the idea of parents using the website to connect with other parents within the study that have similar children (autistic) and compare similar environmental exposures. The website could be used to form support groups or message boards.

4.0 Overview of the NCS Focus Groups

A total of 32 focus groups were conducted in 14 locations under two work assignments. Participants in the first series of focus groups included five stakeholder groups: expectant parents, parents of children with disabilities, parents of children without disabilities, health care providers, and community representatives. Participants in the second series of focus groups were members of eight different racial and ethnic groups, couples who are trying to conceive, pregnant teens and teen mothers, and two groups of pregnant women and mothers who discussed biospecimen collection. This section provides an overview of the themes, issues, and concerns identified in the 32 groups.

Part 1: How Do We Get You Interested?

Focus group participants from the first and second sets of group sessions are in agreement that the best place to hear about the NCS is from their doctor or health care provider. The doctor is a person they trust and a person they feel is knowledgeable about their health. In addition, many of the participants noted that they would be more comfortable about participating in the NCS if their primary physician was involved. When developing the role the primary physician will play, it will be important to remember that the health care providers we talked with were interested in participating in the study but were concerned about the workload. They did not think that they would have the time to actively enroll people in the study nor did any of the health care providers believe that they would have the staff to cover the additional tasks related to the study. This was particularly true for the providers who worked in public health clinics and hospitals.

The focus groups participants also mentioned other places that would be good places to learn about the NCS such as hospitals, pediatric and OB/GYN clinics, teen clinics, and special fertility centers. Participants also frequently said that churches, day care centers, schools, and community organizations are good places to learn about the NCS. These are all places they would trust and see as having legitimacy.

Participants in both sets of focus groups agreed that community organizations would be good places to learn about the NCS varied depending on the composition of the group. There was consensus that they need to be respected organizations that serve their special needs or local community. Teens suggested that high schools for pregnant teens and clinics that cater to pregnant teens would be the best places to reach them. People in a number of groups, but especially in the African-American and Hispanic groups, said that Women, Infants, Children (WIC) was a "legitimate" organization. WIC would be a good place to reach lower income families, as would certain government social service agencies that deal with social welfare and employment. Parents of children with disabilities thought that national organizations that specialize in disability issues, such as the March of Dimes, and local rehabilitation organizations would get their attention. Community organization representatives said that hearing about the NCS from respected organizations was important but did not specify which organizations.

Members of specific racial and ethnic communities in the second set of focus groups said that organizations that served their particular local communities would be the best point of contact for the

NCS. African-Americans mentioned the NAACP and the Urban League as respected organizations in the African-American community. The Asian women suggested that specifically Asian events like festivals and Asian service centers and clinics would be good ways to reach the Asian population. One group of Asians thought it was important to educate community leaders so that they could then educate the community. The American Indian women strongly asserted that endorsement by their tribal leadership would carry the most weight, but that tribal centers that deal with maternal health and the Indian Health Service could help people learn about the NCS. One of the Asian groups also wanted community leaders to endorse the study.

Group participants were asked which media (such as TV) or mode of contact (such as phone calls) would be the best way to contact them. For the most part, the second set of focus groups reinforced what was learned in the first set of focus groups. Because group members recommended a variety of media and modes, it would be best to use multiple media or modes of contact to recruit participants. In some groups there was a consensus about which mode was best or worst, and in other groups there was no consensus. Group members preferred TV ads or news items over radio announcements, which no one liked. Magazines for pregnant women and parents were mentioned in a number of groups. Newspaper ads would be an effective recruitment media for some group members, but they disagreed on whether ads in regular or free papers would be most effective. Most participants did not think that ads on buses would be very effective. Participants said they did not ride the bus. Some thought the ads would be covered with graffiti. Most focus group members would not want to be called by someone from the study. They would be concerned that the person might not be legitimate. Or if they have caller ID or call screening, they would not answer a call from an unknown number. Those who were busy with young children also did not have time for long phone discussions. Mail would get the attention of some women but not others, who would throw it away. Focus group members suggested that mail from the study should have a logo or something to catch their eye so that they would know it was not junk mail. Some of the women preferred to be contacted by e-mail. But others did not have e-mail or would be afraid that the e-mail might be spam, be from a hacker, or have a virus. Health care providers said that the best places for them to learn about the NCS were medical journals and professional associations

The racial and ethnic minority groups showed that group newsletters and word of mouth are important sources of information on the NCS. The two American Indian groups suggested that tribal newsletters be used to recruit people from their community. The Asian and American Indian groups said that word of mouth would be one of the most effective ways to let them know about the study, because they would trust friends, relatives and tribal leaders. This set of focus groups also revealed that the American Indian, Asian, and West Indian women and the teens all believe that the NCS should engage elders (or parents) in the study because the views of elders are held to be important.

There was not much difference between groups within and between the two sets of focus groups regarding information they would need to know before they contacted the study. The most important things that they would need to know about the study were confidentiality, risks to the child, benefits, and use of the research data. Confidentiality was a theme that was carried through the groups. Risk to the

child was an important concern. Some participants in 3 groups (Pregnant women 35 years or older, the high risk pregnancy group, and the couples group from the first round) were concerned that the child might be exposed to something harmful, such as chemicals or trial drugs. They wanted to know how their child would benefit from participating. Many asked how the research data would be used. Participants also wanted to know what was expected of them—what they would have to do and how much time it would take. Members of 12 different groups asked about convenience, where the testing would be done, or whether transportation would be provided. The second set of focus groups showed that knowing who was sponsoring the study was important in determining the researcher's credentials. Credentials were especially important to one of the Asian groups and to the African-American couples group. Participants were less concerned about the eligibility criteria for the study, but would not want to waste their time calling if they were not eligible. Community organization members wanted to know the same things as most participants: study objectives, risks and benefits, and confidentiality. Besides the goals of the project, health practitioners were especially concerned with risks, liability, and confidentiality, and mentioned the need to go through the IRBs at hospitals. They were also concerned about how much time it would take and how much it would cost their practice, because for them "time is money."

In both sets of focus groups the participants were asked what would interest them most about participating in the NCS. The most common response was the possible health benefits to children. They would be excited to receive information on child health and the environment. Individuals with particular health concerns or issues wanted to receive information on particular diseases and cures. Community representatives said that obesity, asthma, lead poisoning, air quality, cigarette smoke, water quality and diabetes were examples of important community health issues. In the first set of groups, the parents with children with disabilities and the group that goes to public health offices (which was an African-American group) said they would be excited to receive information about particular diseases and health issues with which they were concerned. In the second set of focus groups one American Indian group and the Mexican-American group were especially interested in receiving this kind of information. Being part of a large national study was a draw for people in nine of the groups, but this would not make them feel "excited" (except for one of the parents of children with disabilities groups.) Knowing someone else in the study was not important to most groups. Most of the women said that they would be more interested in participating because they were pregnant and the two groups of parents of disabled children said they would be more interested in participating because child had a disability. If the experience of the first child was good, the pregnant women groups (from the first round) would allow a second child to participate. Community organizations would be interested in funding for their organizations and recognition for their role in the project. Alignment of the project goals with the goals and missions of their organizations was also very important. Medical practitioners were excited about the contribution of the research to public health and science, but also mentioned professional gain. They would be more interested if the study addressed particular health issues with which they are concerned

Focus group members from both sets of focus groups said that having a spokesperson for the study would be helpful but they differed on who they thought would be a good spokesperson. Many felt that having a celebrity as a spokesperson would not be good because the celebrity would be getting paid

to market the study without being personally invested in it. Of those who thought a celebrity would be good, Oprah Winfrey was the most commonly mentioned individual, although one group said she would not be a good spokesperson because she does not have children. The First Lady Laura Bush was mentioned a couple of times. One group mentioned Dr. Spock but they were not sure if Dr. Spock was still alive. The best spokesperson would be a mother. Some felt it should be a normal mom and others thought it could be a celebrity mom. Some groups also like the idea of having a medical expert as spokesman, like the Surgeon General, but others thought that this would be boring and a “turn off.”

The first set of focus groups suggested that who was seen to be an appropriate spokesperson varied according to special concerns or composition of the group. Couples concerned with fertility issues preferred the spokesperson to be a medical expert. The two groups of parents with disabled children wanted a spokesperson that had first hand knowledge of disability issues. They suggested Doug Flutie, the football player who has an autistic child, or a Special Education professor. The need for a spokesperson that people of a particular community can relate to was also seen in the second set of focus groups, particularly in the racial and ethnic groups. The teens, who were mostly African-American, liked the idea of having an African-American spokesperson, such as Oprah Winfrey or Whoopi Goldberg, or a teen mom. The African- American and non-African-American black groups suggested Oprah Winfrey or an African- American child advocate. The Hispanic groups disagreed on their choice—one group suggested a non-celebrity mother and the other group recommended the Surgeon General. The Asian women did not name any particular individual, but one group emphasized the role of the community leaders in promoting the study. The American Indians were very explicit about wanting a Native American spokesperson. It would be best if it were a tribal leader. But they also mentioned a Native American celebrity mother.

In both sets of focus groups, participants generally said that both the contribution to their child’s health and overall public health or science were important. There may have been a social desirability factor at work here such that people did not want to say that they wanted the study to help only their child. It was not clear that participants knew what “public health” was other than the “health of all children.” Except for one group, they did not distinguish public health and science. The racial ethnic groups in the second set of focus groups elucidated fears about inclusion and exclusion. People in one of the American Indian groups (Seattle) did not like the idea of “contributing to science” because it sounded like their group would be experimented on. Both American Indian groups were very concerned that the study should include them. They said that they are often left out of studies. They both emphasized the importance of the study to understanding the health of their community. In contrast, groups with a large number of African-Americans in them emphasized that their community should not be singled out for research or experimentation and brought up the Tuskegee study.

Part 2: What About the Time Commitment and Data Collection Activities?

While in both sets of focus groups a common initial reaction was that the level of participation was too much, most focus group members then agreed that it was acceptable if the doctor visits were piggybacked on their regular well child visits. All the groups wanted to see their own doctors rather than a

study doctor. Many thought that there were too many visits the first year. In the first set of focus groups the parents of disabled children, whose children would have to go to more doctor visits than children without disabilities, thought that there were too many visits in the early years. Some groups said that the one hour visits were too long. Group members wanted flexibility and convenience. They would prefer it if home visits could replace some of the office visits. They were also concerned about the logistics, especially how far they would have to travel to testing sites. For some, providing transportation would make the difference in whether they could maintain the required level of participation. They mentioned travel vouchers and being picked up and taken to appointments.

The teen, racial-ethnic, and couples groups in the second set of focus groups revealed some new information about the level of participation. The African-Americans and Mexican Americans thought that there should be more visits when the child is age 7 to 21. They said that the visits should be every year, rather than every other year. One American Indian group (Albuquerque) would like to get a second opinion on their child's health. One Asian group (Los Angeles) and one American Indian group (Albuquerque) liked the idea of getting extra health care, beyond what they would normally get, through participation in the study. Transportation was especially an issue for the African-Americans, the Hispanic groups, and one each of the teen and Asian groups. One Asian group also said that if child care were provided, that would make it easier. In the second set of focus groups couples trying to conceive were included so that their special issues could be identified and addressed. The couples said that they were willing to take an initial physical exam and (for the women) a gynecological exam before pregnancy.

In both sets of focus groups participants generally would agree to collection of environmental samples. All would want to know why the tests were being done and would want to receive the results. They did not think the number of visits was excessive. Even within many of the groups participants were split on whether they would like to collect the samples themselves with a kit or have someone come in to take the samples. Those who wanted to do it themselves cited the convenience. But they would want to have good instructions and pre-paid containers to mail in. Those who did not want to do it themselves said they might do something wrong and contaminate the sample or they would forget to mail it in. If someone came in, it would be important that they have an appointment. A few people said that they would either want the same person to come in each time or that they would want a woman to do the collection. Whoever came in would need to have identification linking them to the study. Some focus group members wanted to know whether the study would intervene to correct any environmental problem they found in the home and some said that they should also do these environmental tests at the schools and day cares.

Some fears relating to the environmental sample collection emerged in the first set of focus groups and was repeated in the teen and racial and ethnic minority groups. In the first set of focus groups a predominantly Hispanic group (the group of pregnant women with less than a high school education) expressed the fear that the researchers would act "like social workers" and judge them to be "bad mothers" if their house was dirty. The view that they would be viewed as "bad mothers" was reiterated in one of the teen groups. The Seattle American Indian group went even further and said that it would have

to be clear that the collector was from the study and not from Child Protective Services (CPS). One of the American Indian groups expressed a different kind of fear. They were scared by the words “environmental samples,” and said it was better to just talk of “dust and tap water samples.”

In both sets of focus groups the participants did not have a problem with completing a survey periodically for the study. Some, however, would not want to do this more than 2 or 3 times in a year. Group members liked the idea of the survey replacing one office visit. Some individuals said they could fill out the survey while they wait at the doctor’s office. Groups were mixed in terms of which mode they would like to use to complete the survey—mail, phone, or email. Here again they wanted flexibility in the form of a choice of modes. In the second set of focus groups, couples were asked whether they would be willing to keep a sexual activity diary and answer questions on the survey about their sexual habits, health history, and occupational and other exposures. Both couples groups were willing to provide this information.

Questions about the collection of the various biological samples yielded a lot of interesting information and some differences between groups. In the first set of focus groups, participants were presented with a long list of biological samples and asked about their reactions to the list as a whole. The moderator’s guide that was used in the first set of groups did not explain how or why the samples would be taken. The results of these groups showed that presenting all of the samples at one time tended to evoke the reaction that the study would be overwhelming, burdensome, and intrusive. Also, because the moderator asked about all of the samples at one time, there was not a lot of detailed information about each individual sample. In the second set of focus groups, there was a separate question about each type of sample. The reason why the sample would be taken and how the sample would be taken were also explained. This procedure resulted in richer data and more information from the groups.

In both sets of focus groups the members of each group wanted more information on why the tests were being done and what would be done with the results of the tests. Some would also want to know how the samples would be stored and disposed of. There was concern that the samples might not be used for the reasons that they were told and that the samples might get into the wrong hands. While there were a small number of individuals in the groups that said they would not provide any biological samples, most would provide at least some of the samples.

Most focus group members would provide samples of their own urine and blood when they were pregnant and samples of child urine and blood. With respect to the child, they would not want the sample collection to cause pain. Urine collection was not seen as a problem. Only the logistics of getting a sample from an infant were of concern. Many did not want a catheter to be used to get a child urine sample. Some were only willing to have the child give blood through a finger prick rather than have blood drawn into a test tube. They said that their children were afraid of needles, and many visits to the doctor to give blood would scare them. Focus group members were more willing for the samples of child urine and blood to be taken during regular visits to their own doctors. Then the doctor could just take a little extra for the study. But some said that blood collection was a “turn off.”

The second set of focus groups brought up new issues relating to blood sample collection, issues that were sometimes specific to a particular group. While a number of groups mentioned that they would not want the study to put anything into the child, like drugs or inoculations, the Chicago couples group was particularly concerned with this issue and confused blood taking with inoculations. One teen group was especially concerned that the government might use the blood in some way that would hurt them. The group that had a real problem with giving blood was the Los Angeles Asian group. They said that blood was “precious” as the source of life. Giving blood would make them feel faint and they would then need to eat a couple bowls of rice to recoup their energy. They said also that Asian women have small veins and that therefore it is difficult and painful to give blood samples.

The placenta collection was not well received among many focus group members, except for those who said they did not care because it was just thrown out otherwise. There was strong resistance to giving the placenta in 8 groups, although it was not necessarily unanimous within the groups. Some thought that the placenta was too personal, or that its collection was just gross. Others were concerned with cloning. Medical practitioners also said that they thought that people would resist giving the placenta for fear of cloning. Some participants thought that collection of the placenta would mean either that they themselves would have to collect it right after the birth or that it would mean that a stranger would be present in the delivery room to collect it.

In the second set of focus groups the teen and American Indian groups were most adamant that they would not give up the placenta, although they gave different reasons. The groups that had the most negative feelings about giving the placenta were the American Indian groups. Both groups said they would not give the placenta for cultural reasons. For them the placenta is sacred. The placenta is a bond between the mother and child, and being a mother is a special role in the community. The placenta is used in a ceremony to protect the child. Giving up the placenta would be to go against tribal tradition. If they did give this sample, they would want the results to go to the tribal leadership. One teen group strongly opposed the donation of the placenta for reasons associated with lack of trust in the researchers. They were afraid that the study would do secret experiments on the placenta.

In the first set of focus groups the umbilical cord blood was one of a long list of samples asked as part of a single question, while in the second set of groups there was a separate question about the umbilical cord blood. In the first set of focus groups many participants were hesitant to provide the umbilical cord blood. In the second set of groups it became evident that although many group members were hesitant about providing this sample, they would be willing to provide the sample if they could keep a personal reserve of the blood so that they would have access to the stem cells. For example, members of both biospecimen groups and both couples groups said that they would give the sample but they would want access to the cord to get stem cells if they needed them. A majority in four other groups (pregnant women groups from the last round) opposed the donation of the umbilical cord, but their reasons were not clear. In those groups, people seemed opposed to give a lot of the samples.

Most of the group participants in both sets of focus groups were willing to give samples of breast milk. They particularly liked the idea of receiving a breast pump, which would make the collection

easier. Some women mentioned that they did not breast feed their babies and a small number of others thought that 2 ounces was too much milk. Women who did not want to give breast milk said that it was painful to take the sample, that it would be denying the baby milk, or that it was just too personal. Both the community organizations and the medical practitioners said that they thought that women would not want to give breast milk samples. The medical practitioners mentioned that the women might be afraid that the study was testing for evidence of alcohol.

There was no difference between the first and second set of focus groups with respect to giving the meconium. Giving this sample was thought to be gross but most group members would give it. In six groups most of the women were opposed to giving a meconium sample. Community representatives thought that collecting this sample would meet resistance. A few women in the groups were concerned because they said that the baby's first bowel movement had been when the baby was still in the womb and did not know how this sample could have been collected. Still others were worried about how they would collect the sample until they were told that a nurse could collect it using a diaper. However, many women said there was no problem giving the sample because otherwise it would just be thrown away.

Most of the parents in both sets of focus groups did not believe that providing fingernail clippings was a problem. Their concerns were largely about how to avoid cutting the child's fingers. Some parents recommended clipping the nails when the child is sleeping as one approach. A parent of a child with a disability mentioned that it would be hard to get a nail sample from her child because he chews his nails down.

While fingernail clippings did not pose a problem for the parents, the collection of hair samples did for some of the groups. The reasons for not agreeing to provide a hair sample were quite diverse. Some parents said that their children had very little hair and that collecting a sample may not be possible until they are a few years old. Some African-American participants mentioned that many of their boys wear their hair very short and it would be difficult to get a sample. This group also mentioned that their hair is difficult to grow and they would not be willing to cut even a small sample. There were also some trust issues associated with the giving of hair samples. Some participants (including some of the teens) were concerned that the government could get DNA from a hair sample and the DNA might be used against the child if he had a problem with the police in the future. A few other participants were concerned about drug testing.

The first set of focus groups did not reveal any strong feelings about giving hair samples. However, the focus groups with American Indians and some African-Americans, Hispanics and non-African-American Blacks indicated that giving hair samples was strongly opposed on cultural grounds. For fear of witchcraft, the American Indian women would not agree to provide a hair sample. Hair is considered sacred, like the placenta. If you cut your hair, you burn it so that it will not fall into anyone else's hands. Even if they agreed to provide the hair sample in the clinic, they would worry that there might be some conflict between the nurse's family and their own family. If they consented to give hair, they would want to watch it being taken and would want the hair to be returned so that they could burn it. If they agreed to it at all (and most would not agree), the hair would have to go through only one person's

hands and that person would have to be trustworthy. Some of the African-American and Hispanic women cited the use of hair in Voodoo as a reason for not agreeing to provide a hair sample. Also, the women from the West Indies cited a cultural practice of not cutting a child's hair until after the child learns to speak.

The collection of buccal cells met with much less resistance in focus groups of both sets. Almost no one objected to the collection of buccal cells. Some parents worried about possible pain the sampling might cause the child. Those who were concerned about giving the buccal cells understood the buccal cells to be primarily a source of DNA. The group of teens who opposed the collection of hair samples because it contained DNA also opposed the collection of buccal cells.

Even after providing more information in the second set of focus groups about why baby teeth would be collected, most of the mothers in the groups said that they would not give up the baby teeth, at least not the first tooth. The reasons were primarily because the baby teeth have sentimental value. After some discussion, many women said that they would be willing to give up teeth as long as they were not the first teeth. A few of the parents of children with disabilities said that their children had swallowed all of their teeth or lost them when they fell out. A few parents did not understand that the collection would only occur after the tooth fell out and were relieved to hear that the teeth would not be pulled out. The second set of focus groups showed that some of the participants in the African-American group would agree to testing if the teeth could be returned to them.

Agreeing to genetic testing raised a number of issues. For the most part, participants did have some idea about what genetic testing involved but clearly this is not a topic that any group was well-versed on. The group of women who were over age 35 had the fewest questions or concerns. This was likely because they had been provided information about genetic testing during their pregnancy. Most participants in both sets of focus groups agreed to genetic testing under certain conditions. They wanted to be insured of the confidentiality of the results and they wanted to be certain that the results were not provided to anyone other than their health care provider. One big concern was that the information would be provided to insurance companies who would use the information to deny future coverage. This concern emerged in the first set of focus groups and was reiterated in the second set crossing all groups. The biospecimen group (conducted in RTP) raised the issue of the new HIPPA regulations. Some participants were also worried that their genetic information would be put into a government DNA database or on a list that would be used against the child in the future if the child got into trouble with the law.

Most participants thought of genetic testing as primarily a way to test for disorders. One individual, an African-American from the pregnant woman group that goes to public health offices, was afraid that the testing could show a predisposition in her son to become a murderer. Some focus group participants did not understand what genetic testing entailed. They were afraid that the testing might be painful, risky, or invasive to their child. In one group of parents of disabled children the participants were afraid that genetic testing involved inoculations. While most people who would consent to the testing wanted to receive the results, some did not want the results if they could not be interpreted or if they

indicated a problem. For example, the woman who was afraid that the testing might indicate that her son was a future killer did not want the results. Some said that they would want the results to go to their doctor, who would then interpret them, or that they would want a genetic counselor. Medical practitioners themselves said that they would not feel comfortable interpreting the results of genetic tests. They also pointed to needs for treatment and possible stigma for the individual tested who has genetic problems.

Participants were asked at what age the child should sign his or her own consent form. Almost all thought that the appropriate age would be 18. However, ages mentioned ranged from 11 to 21. The second set of focus groups showed that pregnant teens and teen mothers have differing views on the appropriate age of consent. Some teen mothers believed that teens who are mothers should be allowed to sign the consent even if they are not 18 because they are acting as adults. Other teens believed that they were not old enough or adult enough to sign the consent forms themselves and thought that 18 should be the age of consent.

Members of a number of groups were concerned about their children not wanting to participate when they got older. Some focus group members said that if their children did not want to participate even when they were younger than 18, they would not force the child. They would leave the study. The non-African-American Black group said that it is part of their culture that the child should do as the parents say. If the parents weighed the pros and cons and decided to participate, the child would have to cooperate.

Part 3: How Do We Keep You Interested?

Discussions of incentives for participation were lively. The second set of focus groups confirmed the findings from the first set of groups and there were no major thematic differences between different racial-ethnic or other types of groups. Almost all group participants believed that they should receive some kind of incentive for participating. The few who did not want an incentive said that the health information would be all that they would want. This occurred in non-African-American Black group. (The Mexican- American group and one couples group mentioned their desire for health information first, before they mentioned other incentives.) However, most people said that information on their child's health would not be an incentive but rather something that they would expect as participants in the study. Only one Asian group reached a consensus that they would like to make a donation to charity, but they wanted gifts as well. Most of the groups said that they thought that gifts for both the child and the parent were appropriate. For the parent the gift would show appreciation for their time. Gifts to children should be age appropriate and should stay current with the times. One group thought that incentives should be greater in the first year because the demands on time were greater. Most groups thought that gifts should increase the longer you are in the study. Here again many wanted flexibility. They wanted to be able to choose from a list of incentives. Many focus group members did not like the list of incentives that was handed out or thought the list was too narrow. One group of pregnant women (suburban women who go to doctor's offices) thought that the list was geared to first time moms only, while another pregnant

women group (white women under 35) thought that the list was not only targeted to first time moms but also to lower income women.

Focus group members had clear likes and dislikes regarding gifts. On the low end, group members preferred gift certificates to coupons because they did not have to put up any of their own money with a gift certificate. (One group thought that coupons should be included with the survey.) Group members especially liked gift certificates to national chain stores such as Wal-Mart. They were not interested in child photos and generally preferred to receive gift certificates or money for school supplies or clothing rather than toys. They proposed other gifts for the child that were not on the list, including tickets to events, payment for classes, books, camp or field trips for the child, and membership in clubs. One of the parents of disabled children would like a vacation. Occasionally the women wanted something special for themselves such as a spa day or a pedicure. Generally, focus group members were not interested in cable TV subscriptions, Internet access or Web-TV. They especially did not want their children to have Internet access because of all the predators that are out there online. Many thought that electronic equipment would be appropriate gifts for older children. On the high end, most of the groups asserted that there should be a big reward for people who stay in the study until the end. They suggested college tuition, savings bonds, or IRAs for the child. Community representatives would like recognition for their role in the study and increased access to information. Medical practitioners would like professional development opportunities and luncheons for staff who are involved in the study.

There were some interesting findings relating to particular groups with regard to gifts that emerged in both sets of focus groups. One of the couples groups thought that there should be money for fertility tests and drugs and that if you cannot conceive a child you should still receive gifts. In the first set of groups pregnant women who do not have health insurance said they wanted to receive health insurance as an incentive. In the second set of groups both Hispanic groups said that they would like to receive health insurance. The group of pregnant women without insurance also mentioned money for prescriptions, medical supplies, and dental care. Perhaps reflecting their economic condition, one of the teen groups wanted very practical things such as Section 8 housing or rent vouchers, furniture, a stove or refrigerator, and clothing. One group of Asians, as well as some individuals in other groups, suggested that the study have parties so that participants could meet each other and socialize. The second set of focus groups showed that teens and Asians wanted some kind of recognition for participation in the study. This was a new idea that was not mentioned in the first set of groups. The Asians viewed participation in the study as an honor. They thought it would be good to give the child a certificate for participating in the study, a certificate that he could be proud of and show to his friends. They also liked the idea of mothers who are participating in the study being able to earn educational credit for their participation. Similarly, one group of teens wanted to be able to put participation in the study on their resume.

There was no consensus overall (in both sets of focus groups) on whether they should receive a gift or money for each biological sample collection or each doctor's visit. Often there was no consensus within the group. Some focus group participants felt that getting gifts or money for giving samples was wrong because it was like selling your child. The pregnant women who go to public health offices said

that receiving money for samples would be like a bribe. The Albuquerque American Indian group reached a consensus that they would not want gifts or money for biological samples. Others thought that there should be money for samples because you are giving up something precious. Many group participants were more comfortable talking about gifts or money per visit, rather than per sample. Some thought that there should be a small gift for the child at each visit, a gift like a book or a toy. The Seattle American Indian group expressed a desire to receive gas money for each visit.

Focus group members generally preferred cash to gifts for themselves, although they thought gifts to children were appropriate. They would say things like “cash is always good.” As reported above, some focus group members thought that a certain amount of money should be paid per sample or per visit. They also wanted money for participating in the study to be paid incrementally year by year and at the end of the study. There was no agreement on the amounts that would be appropriate for the study to pay. It was difficult to pin down group members about the amounts that should be paid and it was not always clear what the time frame was for the amounts mentioned. Amounts that were mentioned included \$50 to \$100 per visit and \$200 to \$500 per year. At the end of the study they wanted a lot of cash to be available in the form of the IRA, savings bond, or tuition account. The exception was the Albuquerque American Indian group, which wanted things rather than cash, especially school supplies. Community members would like funding for their organizations in return for support of the project. Medical practitioners would want subsidized labor for copying patient records and a per patient reimbursement.

Most focus group members said that none of the incentives discussed would make them feel that they had to participate or had no choice unless the incentive was really large. If the incentive was too large they might feel uncomfortable or suspicious. But they were generally unable to say what amount would be too large. One of the American Indian groups said that receiving computer equipment would make them feel compelled to participate, while one Asian group said that electronic equipment would make them feel that way. The pregnant mothers who go to public health offices group said that it would be bad if they came to depend on the money from the project to get by. On the other hand, some focus group members were concerned that if the gifts were too large, they study might become bankrupt and shut down.

Participants were asked a series of questions about how the study can keep them informed. How they wanted to receive information depended on whether the information was personal test results or general study information. There was agreement between the groups of the first and second sets of focus groups. They wanted their own test results to come to them in a private and secure way (such as personalized mail or a password protected web site) or directly from the doctor. They said that they did not want to get other people’s results. General study information could come via a number of more public media.

Most participants from both sets of focus groups preferred to be contacted about study information via mail, email or newsletters, but meetings and phone calls were also mentioned. All information must be written in “plain English” so that they can understand it. If information came in the mail, it would be easier to spot and distinguish from the junk mail if it had a study logo. Many

participants liked the idea of getting updates via email or through a study web site. A couple of the groups of pregnant women (first round) also mentioned chat rooms so that they could network with other participants. But participants said that not everyone has access to email or the web. Emails would have to be clearly distinguishable from spam and safe from hackers. Over half the groups liked the idea of receiving a newsletter. Fewer thought meetings would be a good way to learn about the study. Some of those who did not like the idea of meetings said that they would already be spending a lot of time on the study and would not want to attend. Most focus group members would not want to receive phone calls about the study results, although some would like to have an 800 number that they could call at their convenience. If they received calls they did not want them to be automated. Rather, they wanted to talk to a person. Two groups wanted to have a choice of contact mode. Community members requested updates via newsletter, a website, or meetings. They also would like to see a community advisory board set up. It was important to them that the study results be widely disseminated. Medical practitioners in both groups wanted updates in newsletters, email, a study website, or meetings with study staff. They also wanted to hold meetings with their own staff.

Group members from both sets of focus groups distinguished again between personal test results and general study information when they discussed their desires for updates. They thought that they should receive personal test results after each visit to the doctor. They wanted the information quickly so that they can take action quickly if there is a health problem. Although some mentioned monthly and annual updates of study information, most preferred to receive this information quarterly or every 6 months.

There were a lot of similarities across groups in both sets regarding what kinds of information study participants would want to receive. They all wanted to receive personal test results and study information. Most thought that the study should update them on findings and the use of the information, especially how it is helping people. One of the American Indian groups requested information on what tests would be performed, so that they would know what to expect. Two groups said they would like to receive summaries of state or regional findings so that they could look at their personal results in the context of the larger study. Three groups wanted a bibliography or references to literature on health and the environment.

Most of the participants in all of the groups reacted to the question about whether there was any information that they would not want to receive by saying that would mean the study was hiding something from them. Most wanted the results of all their tests even if they can not be interpreted. The exceptions were the pregnant group without insurance, who said that they did not want information if they can not do anything about it, and another pregnant group (suburbanites with more than high school education) said that they did not want the results if they cannot be interpreted. As mentioned above, while many participants would want to have their doctors interpret the test results, the doctors themselves would not feel comfortable interpreting the results.

Part 4: Barriers to Participation

In this section we present an overview of concerns and barriers and ways that the study could make participation more attractive or overcome barriers. While most focus group participants said they would participate in the study, most expressed concerns that would present barriers to participation.

The most important barriers to participation involve trust issues, some of which were mentioned earlier in this report. Focus group members had issues relating to the legitimacy of the study, the handling and use of samples, confidentiality, and general distrust of research or the government. One Asian group and a couples group would need to see that the researchers had credentials and the two teen groups were concerned about the legitimacy and accountability of the project. Participants in all groups said that if they could not get the results of their tests they would be suspicious about the study. Many were also very concerned with where the samples go, who handles them, and how they are stored. The group of pregnant women without insurance, the Mexican Americans, and the American Indian groups were especially concerned about the handling and storage of the samples. Some group members were afraid that the study might do secret tests on them or do different tests than they said they would do.

Issues of mistrust of research, mistrust of the government, and institutional racism emerged in the course of the first set of focus groups. These issues were particularly prevalent in the groups in which there were a significant number of racial-ethnic minorities. African-Americans, especially, voiced these concerns, sometimes pointing specifically to the Tuskegee studies. These findings were an important factor in the decision to include a variety of racial-ethnic minority groups in a second set of focus groups. In the second set of focus groups the African-American group and African-Americans in other groups again cited the Tuskegee study where participants were used as “guinea pigs” in research. The teen group that was all African-American said they would be afraid that the study would target minorities and specifically would “experiment on black people.” Community members in the first set of groups had also said that this mistrust of research would be an issue for African-Americans in the study. American Indians were afraid that the Indian Health Service or the NCS would conduct secret research. One group brought up the case of a rogue researcher who conducted illegal experiments torturing mice. The parents of children with disabilities, the pregnant women who go to public health offices, both American Indian groups, the African-Americans, the Mexican American group, the teens, and one biospecimen group made it clear that as a group they distrusted the government or research studies.

Another area of mistrust related to use of the test data. In both sets of focus groups people in a variety of groups wanted to be sure that the data were used for the right purpose and that the data did not fall into the wrong hands. The pregnant women who go to public health offices and the teens were afraid that the samples might be used to test for drugs. Community representatives reiterated that fear of drug tests or tests on sexual behavior would frighten some participants. Focus group members in many of the groups were concerned that insurance companies would somehow get the results of tests and then deny coverage. Members of six of the groups were especially concerned that genetic information might be put into a data base or given to insurance companies. Some feared that later in life the child would be stigmatized if something genetic was wrong. The child might not be able to get into the military. Or the

courts or law enforcement may get the data and use it against their child if he got into trouble. These fears were especially prevalent in two groups in the first set—the groups of pregnant women without insurance and pregnant women who go to public health offices—and two groups in the second set—the Other Hispanics and one of the biospecimen groups. An African-American couples group was concerned that the data might be misplaced.

Across the groups some individuals said that collection of particular samples would be a barrier to participation. Here the second set of focus groups with the various racial-ethnic minorities contributed new information. For American Indians collection of the placenta and hair would be a barrier. The Asians said collection of blood would be a concern. The non-African-American Black women indicated that collection of hair from infants would be an issue, but said they would be willing to participate if their whole family agreed. Two groups—the Mexican Americans and the Los Angeles Asians-- indicated that if researchers did not speak their language, this would be a barrier to participation. The Asians would also prefer to have their own Asian doctors. Participants would not want to participate if there was any risk to the child or if the study procedures were invasive, for example if the child was exposed to chemicals or given drugs or inoculations. They would also be less interested in participating if they could not go to their own doctor, if they could not piggyback on regular well child visits, or if the testing sites were not convenient.

When asked what the NCS could do to address their concerns, focus group participants said that they wanted as much information as possible. The study staff should tell them up front what tests will be performed and why they will be performed. They should also be told how samples would be handled, stored and disposed of. Those who do not want to give particular samples should be educated on the purpose of the samples and be made to feel comfortable giving them. For example, although American Indians have traditional reasons for not giving their hair to other people, they would weigh the health benefits against the risks. They might agree to donate hair samples if the samples were only handled by one trusted individual and the hair is given back to them so that they could burn it.

The study should also guarantee confidentiality, ensuring that only study staff would see the results of tests. Test results would never be released to insurance companies or law enforcement. A safeguard that one of the couples groups mentioned is making sure that HIPPA regulations were followed. Genetic information should be especially closely protected. One group wanted it to be legally protected.

Research staff should have credentials and these credentials should be shown to study participants, according to one of the couples groups and the Asians. Having credentials bestows legitimacy. The Asians would also like to receive information on past studies and how this study relates to them. The study staff should also give participants specific information on how the samples would be used and should guarantee that the data would not be used for other purposes, even if the course of the study changed mid-stream.

Organizations that convey information to potential participants must be respected national organizations (like the March of Dimes, the NAACP, or the Girl Scouts) or local organizations that are

trusted by their community. Making sure that their own doctors are an integral part of the study would be critical to focus group members. Endorsements by community organizations (the Asians and African-Americans) or tribal leadership (American Indians) would help address their concerns and lend legitimacy to the study. The American Indians probably would not participate without the approval of tribal leaders. The study should also make it clear that participants come from all racial/ethnic groups and that no group was either singled out or excluded.

5.0 Recommendations

The purpose of the NCS focus groups was to gather information from the major stakeholders in the NCS to inform decisions about the most efficient ways to approach the recruitment and retention of participants into the NCS. Identifying the most efficient approach to reach the targeted demographic will insure a successful recruitment effort. The information gathered from the focus groups also will be used to inform the retention plan to reduce attrition by identifying the issues that would make continued participation in the NCS a rewarding experience. The recruitment and retention plan needs to anticipate and respond to the concerns of potential participants about long-term commitment to the study. The goal is not to induce compliance with a single task but to gain the full cooperation of each participant. To achieve this goal each participant needs to believe that he or she is a partner in the research and not a “research subject.” The recommendations described in this section are based on a carefully integrated review of the information gathered from the 32 NCS focus groups.

To successfully recruit and retain 100,000 participants in the NCS, researchers will need to have a thorough understanding of the issues that affect the stakeholders' motivation and ability to participate in the study. There is an extensive literature on the social psychology of persuasion that indicates that there are two routes to persuasion: the central route and the peripheral route (Eagly & Chaiken, 1993). Attitudes formed through the central route are the result of extensive evaluation of the information presented and are therefore more predictive of future behavior and more resistant to change. Attitudes formed through the peripheral route are generally formed quickly based on cues in the environment rather than on extensive issue-relevant thought. Attitudes formed through this route are generally subject to change and are not predictive of behavior.

Through the NCS focus groups we learned a great deal about the issues that the stakeholders in the NCS feel are important to them. Based on what was learned in the groups, the approach to the recruitment of pregnant women in the NCS will need to include:

- an informational campaign that addresses the issues identified by the focus groups as important and personally relevant for each of the stakeholder groups;
- a clear statement of the expectations of participation and the potential costs and benefits to the stakeholders; and,
- a consistent approach to retaining participants.

The approach to raising awareness of the NCS among the target demographic and gaining their cooperation needs to be tailored to each particular group of stakeholders.

Expectant parents were in agreement that the place they would most likely learn about the NCS is at the doctor's office. This is the place they expect to learn this kind of information and the doctor is a person they trust. Although the doctor's office is a logical place to disseminate information about the NCS, this approach would limit the enrollment to those seeking prenatal or preconception care and would miss women who do not seek medical care. Community groups can help fill the gap by disseminating information about the study to potential participants. Going through the community groups will allow the

NCS to target the appeal to the appropriate demographic insuring that the costs and benefits described are appropriate to the community. In addition, the support of the community groups helps to confirm the legitimacy of the study to potential participants, increasing the likelihood that they will agree to enroll in the NCS.

The information gathered in the individual focus groups will be critical to the development of the targeted informational materials because it defines what questions and concerns that particular demographic has identified as key to gaining their commitment to the study. Although, all groups agreed on five basic questions that would need to be answered by the study's outreach materials before they would contact the study staff about participation, there are concerns that underlie each of these questions which are unique to the various groups of women who will be participating in the NCS.

The five basic questions all groups asked were:

- Who is sponsoring the study?

Several groups noted that knowing the sponsor of the study was an important factor in determining the researcher's credentials and the legitimacy of the study. However, some groups raised additional concerns about special interests—government or corporate—that might reduce their confidence in the legitimacy of the study. Special interests or corporate sponsors should be disclosed at the outset and their role in the study explained.

- What are the eligibility criteria?
- Participants' interest in eligibility was primarily so that they did not waste time exploring something for which they were not eligible.
- What are the expectations for participation?

How the NCS frames the required activities and expectations for participation in the NCS will be critical. Focus group participants were adamant that they would want clear specifications about what would be expected of them. However, providing too much information may cause potential participants to feel overwhelmed if the information is not presented with an easily understood rationale. One important lesson learned from the first round to the second round of focus groups was that the women were much more agreeable to providing the biospecimens when they were presented with the information about each specimen individually with some explanation for the purpose of the collection and testing.

In addition to presenting the expectations for participation, it will be important for the NCS to present an understanding of the potential participant's lifestyle and the ways that the NCS can offer to reduce the burden of participation. For example, the issue of transportation was raised in a number of groups--rural folks needing to get into the city; low income participants who cannot afford transportation; and, busy parents who do not have time for lengthy trips on public transportation with small children.

Convenience and flexibility were universal concerns, and should be emphasized.

- What are the risks and benefits to my child?

Information about the risks and benefits of participation will be critical to gaining the cooperation of potential participants. The focus group participants were very concerned about risks of participation to the child. They wanted to be sure that the child would not be exposed to something that he or she would not normally be exposed to. The study materials and consent forms will need to be very clear and easy to understand. Participants will need reassurance that the study has taken all necessary precautions and will not put their child through any undue pain or suffering. Although, focus group participants said that both the contributing to their child's health and to the overall public health or science were equally important, the materials should emphasize personal benefits to the child and family for all groups followed by benefits to overall public health and children's health. The language used in outreach materials will also be important. Participants in the American Indian group (Seattle) did not like the idea of "contributing to science" because it sounded like they would be the subject of experimentation. The focus group participants were in universal agreement that one benefit that they saw in participating in the NCS was receiving the results of the physical examinations and tests.

- How will the study protect the confidentiality of my information?

Confidentiality was also a major concern to participants. The main concern was that insurance companies would get the records and deny coverage. A second concern was that the government would build a data base that can be used in criminal investigations or to deny entry into the military. A third concern was about drug testing for the use of illicit drugs. A related concern was that information gathered would be used to deem the parent as unfit and remove the child from the home. The issue was raised in several groups but perhaps most strongly in the teen groups. This raises an important concern about reporting neglect and abuse which will need to be addressed in the consent forms. All participants will need to be made aware that NCS staff will follow the guidelines for reporting abuse and neglect as defined by the state in which the participant resides (or whatever policy the NCS adopts).

The recruiting plan should also include information that focus group members said would excite them most about participating in the NCS. The list includes receiving information on:

- Child health and the environment
- Diseases and cures for illnesses
- Community health issues: obesity, asthma, lead poisoning, air quality, cigarette smoke, water quality and diabetes
- Diseases and health issues special to a racial/ethnic group
- Being part of a large national study

Based on the responses of the focus groups, the NCS should have more than one spokesperson. The focus group participants agreed that the spokesperson should not be a show-business celebrity but rather a well-known person who is a parent who has demonstrated an interest in children's health. The

surgeon general was recommended by many participants as someone who has medical credibility and has demonstrated an interest in children's health. The racial and ethnic groups all indicated that they would like to see someone who shared their racial and ethnic background. This would suggest a group of spokespersons representing the diversity that would be key to the success of the NCS.

The challenge to presenting a clear message to potential participants about what would be expected of them during their participation will be to provide clear and accurate details without overwhelming them with information. A second challenge will be how to communicate changes to the protocol as the NCS evolves without undermining participants trust in the study.

Overall, the major take home message from the focus groups was "convenience." The majority of focus group participants agreed that the number of visits suggested as a possible scenario were acceptable if they are combined with regular well-child office visits and if transportation was provided (if necessary).

Focus group participants generally would agree to collection of environmental samples. A plan should be in place to allow self-collection if the participant chooses. Those participants in the focus groups who wanted to perform the collections themselves cited the convenience. This would require clear instruction and training but has been demonstrated to be a feasible method for this type of collection.

The periodic survey should be developed so that it can be completed in a mode most convenient for the participant--mail, phone, or email. Here again they wanted flexibility in the form of a choice of modes.

The key to gaining cooperation to provide biologic specimens is to provide a clear explanation of how the specimen will be collected, what tests will be performed on the specimen, and the importance of the test results. In the first round of focus groups with the pregnant women and parents only a small proportion of time was allocated to the discussion of the collection of biologic specimens. A list of specimens was presented—blood, urine, breast milk, meconium, umbilical cord blood, placenta, hair and fingernail clippings—and the women were asked how they would feel about providing the specimens. The participants were clearly overwhelmed by the list and confused because they had no idea how the samples would be collected. For this current round, we added the two groups that spent a majority of their time discussing the specimen collection but we also changed the way the information was presented to the racial and ethnic groups of women. We presented each specimen individually along with a brief explanation for the collection and what would be learned. The reactions of the women in this second round of focus groups to questions about the collection of biospecimens were very different from the reactions of the women in the first set of groups. The additional information helped to inform their decision and the request made sense to them. The outcome was that most said that they would agree to provide the biologic specimens. However, we did uncover some very important information about the cultural beliefs of many of the groups which will help to inform decisions about how to approach those groups or if another test can be substituted in the protocol.

A similar approach should be used to asking potential enrollees in the NCS about participating in genetic testing. Most participants knew something about the topic but most thought of genetic testing as primarily a way to test for disorders. There are also some serious misconceptions that should be addressed. For example, one person said that she was afraid that the testing could show a predisposition in her son to become a murderer. In addition to misinformation, some focus group participants did not understand how the testing would be performed and were afraid that the testing might be painful, risky, or invasive to their child. Most focus group participants would agree to the testing but they want reassurances that the results would not be provided to the government or the insurance companies. Similarly there is concern that if something is found to be wrong with the child that the child might be stigmatized if the information were to be released outside of the study.

The incentive package will be an important component of the recruitment and retention plan. The challenge is to put together a package that will communicate appreciation for their participation in the NCS without undermining their motivation to participate. It is important that the recruitment approach appeal to participants in such a way that they become intrinsically motivated to participate in the NCS because it is a worthwhile endeavor. None of the focus group participants believed that the incentives that were discussed, neither the gifts nor the monetary incentives, would be considered coercive. However, there were clear differences in the amount and type of incentive that would be preferred by some participants. Some participants stated that if the incentive was too large that they would be suspicious of the motives of the study. There was also concern that if the incentives were too large that the study would not be able to afford to continue. If a corporate sponsor donates incentives, then the relationship between the sponsor and the study needs to be clearly communicated to participants to avoid the impression that the sponsor has a controlling interest in the study. Clearly, gifts to children should be age appropriate and parents and children should receive some immediate incentive at the time of each activity and then a year-end bonus for completing all tasks.

Maintaining contact with participants between study activities is critical to retention in a longitudinal cohort study and many focus group participants were concerned about how the NCS would track families that move frequently such as military families. NCS participants should have the option of updating their own contact information either by telephone or via a website. In addition the NCS will need to send periodic communications and study updates that can be used to track participants. It also would be important to send a periodic token (e.g., coupons, school supplies) enclosed with a study update to help maintain motivation and interest.

Participants in the focus groups indicated that they would be open to a variety of methods of receiving study information with some participants wanting more frequent updates than others. The key is convenience. Some participants have a greater need for information than other participants. This need can be met economically via a project website with links to reports and articles of interest to participants. The website should also allow for participants to update their contact information and to ask questions about the status of the project and their participation. In addition a newsletter should be sent at least twice a year to keep participants updated and to maintain a tracking data base for participants who relocate.

The project should also maintain a tollfree number for participants to call with updates to their contact information or questions.

Most of the issues raised by the groups as potential barriers to participation can readily be addressed by the NCS. Many of the groups cited cultural beliefs that would make them reluctant to provide some biological specimens. With this knowledge, the NCS research team can decide whether there is another method of collecting the required data that is compatible with their beliefs. If no alternative exists, then the NCS team needs to present the rationale for why the specimen collection is critical to the goals of the study, why there is no other way to get at the same result, and how the achievement of those goals would benefit their specific group. The American Indian women said that the placenta is sacred but if the tribal elders agreed that the tests could be performed without interfering with the ceremony, a compromise might be reached.

Other important barriers involve trust issues, some of which were mentioned earlier in this report. Focus group members raised concerns about the legitimacy of the study and confidentiality. All of the barriers cited could be alleviated by carefully preparing the recruitment materials so that potential participants are educated about the study and welcomed as partners in the research with clearly defined roles and expectations and consistently applied procedures and appropriate rewards.