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## Diverse Perceptions of the Informed Consent Process: Implications for the Recruitment and Participation of Diverse Communities in the National Children’s Study

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### Abstract

We examined the experiences, perceptions, and values that are brought to bear when individuals from different ethnic and cultural backgrounds consider participating in health research. Fifty-three women from Latino, Asian American, Middle Eastern, or Non-Latino, White backgrounds participated in seven English or Spanish focus groups facilitated by trained investigators using a standard protocol. Investigators described the National Children’s Study (NCS) and then asked questions to elicit potential concerns, expectations, and informational needs. Group sessions were audio-recorded, transcribed verbatim, and analyzed using qualitative thematic methods. A major theme that emerged during focus groups was participant self-identification as a member of a cultural group or community when raising issues that would influence their decision to participate in research. A related theme was the belief by some that communities may differ in the ease of participation in the NCS. Identified themes related to the informed consent process included perceived risks, anticipated burden, perceived benefits, informational needs, and decision-making strategies. Although themes were shared across groups, there were cultural differences within themes. Findings indicated that individuals from diverse backgrounds may have different

perspectives on and expectations for the research process. To effectively recruit representative samples, it will be important to address a range of issues relevant for informed consent and to consider the impact of participation on both individuals and communities.

### Keywords

Informed consent; Research participation; Diversity; Culture; Recruitment; National Children's Study

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### Introduction

U.S. minority populations are underrepresented in biomedical research. There are scientific and social justice reasons for using diverse, representative samples in research (James et al. 2008). When people from different ethnic, racial and socioeconomic backgrounds are not included in research, variability within key independent variables is restricted, raising concerns about the reliability and validity of observed associations. Social justice becomes a significant concern when the underrepresentation of diverse groups in research limits both our understanding of the factors that contribute to poor and good health in underserved populations and our capacity to effectively address health disparities. These are especially critical issues for population-based studies that must successfully engage and recruit from varied ethnic and socioeconomic communities, including historically disenfranchised and difficult-to-access groups. The National Children's Study (NCS) is one example of such population-based health research. This multi-site, observational, longitudinal, community-based study will examine the effects of environmental and genetic influences on the health and development of more than 100,000 children across the United States, following them from before birth until age 21. Recruiting a representative sample for the NCS is necessary to contribute to improvements in the health of all children regardless of their ethnicity, life circumstances or social status.

Recent efforts to increase the representativeness of participants in health research have raised questions about the basic assumptions of the informed consent process in culturally and socioeconomically diverse groups (Beskow et al. 2001; Barata et al. 2006; Bhutta 2004; Levy et al. 2010). Insights from community psychologists and other social scientists call attention to the serious ethical and pragmatic issues that may arise when culturally, ethnically and racially diverse communities are recruited for and engaged as participants in population-based biomedical and public health studies (e.g., Flicker et al. 2007; Jenkins 2010; Yick 2007). These concerns are especially relevant to the task of obtaining informed consent. The doctrine and ethical and legal principles of informed consent make several assumptions that have guided consent procedures and IRB reviews for several decades (e.g., Beskow et al. 2001; Thorne 1980) with periodic updating and adaptation of practice (Beskow et al. 2001). However, as Thorne (1980) argued, there is a strong basis for challenging these assumptions for particular categories of research (e.g., ethnographic studies), settings and populations. This is especially true when investigators' limited knowledge of the "culture," lived experiences and life circumstances of individuals in targeted diverse communities precludes a full understanding of what information may be needed to make meaningful participation decisions (e.g., Culture Clash on Consent [Editorial] 2010; Mello and Wolf 2010). The informed consent process assumes a shared perspective and understanding between researchers and potential participants about the described study (Dixon-Woods et al. 2007; Mello and Wolf 2010). Furthermore, agreement to participate is presumed to occur only after an individual has developed an acceptable understanding of the risks, benefits, purpose and general procedures of the study, as well as provisions for the collection, storage, and use of the data (e.g., Barata et al. 2006; Beskow et

al. 2001; Bhutta 2004), In other words, as Thorne (1980) explained informed consent is purported to be consent that is knowledgeable and voluntary made by competent individuals after being presented with a description of reasonably anticipated risks and benefits, explanation of the study's purpose and procedures and information that the person can end participation at any point during the study. However, these basic assumptions may not be equally valid across groups that differ in cultural background, social histories and socioeconomic circumstances (Barata et al. 2006; Beskow et al. 2001; Bhutta 2004; Levy et al. 2010). Cultural and social experiences can influence an individual's concerns, expectations, comprehension, decision-making and motivation regarding biomedical and genetic research (e.g., Barata et al. 2006; Sterling et al. 2006; Marshall 2006), and also provide rules for decision-making and "ways of knowing" in a decision situation (Cohen 2009; Kral et al. 2011; Trickett 2009). Moreover, participants' implicit assumptions about the risks and benefits of participation and the ethical conduct of research can affect expectations for the process, even if consent procedures and documents do not explicitly address or mention these (e.g., Harmon 2010; Levy et al. 2010). Thus, cultural interpretations of the research endeavor and cultural perspectives on ethical issues in research must be considered when members of diverse populations are recruited for scientific investigations (e.g., Harmon 2010; Kral et al. 2011; Mello and Wolf 2010; Yick 2007) and a high rate of consent is necessary for the integrity of the study (e.g., Beskow et al. 2001; Levy et al. 2010). If these perspectives are not addressed or reflected in research protocols, participation rates may be inadequate for certain groups (Levy et al. 2010; Sterling et al. 2006), and misunderstandings may be more likely as the study progresses (e.g., Dixon-Woods et al. 2007; Marshall 2006).

A recent example vividly illustrates possible costs to communities, individual participants, researchers and academic institutions if the cultural and social contexts of informed consent are not fully considered. In 2010, the Arizona Board of Regents reached a settlement with members of the Havasupai Tribe over litigation regarding Arizona State University researchers and ethical issues related to informed consent (Mello and Wolf 2010; Harmon 2010). One issue highlighted in legal documents and statements by the Havasupai people were differences between the perspectives of researchers and participants about what had been consented to regarding the use of collected blood samples (Culture Clash on Consent [Editorial] 2010; Havasupai Tribe v Arizona Board of Regents and Therese Ann Markow 2008; Harmon 2010; Legal Notes 2010). In addition, the legal case revealed the possibility of damage from research participation beyond individual participants to include the broader population or community. A published article based on genetic testing of Havasupai blood samples suggested a theory about the geographic origin of the Tribe that conflicted with traditional stories from elders that placed its origins in the Grand Canyon (Havasupai Tribe v Arizona Board of Regents and Therese Ann Markow 2008; Harmon 2010). These results were seen as threatening to the cultural and social fabric of the society and to the community's claim to certain land rights. Other alleged violations of informed consent principles and practice led tribal leaders to issue an order that banished Arizona State University professors and other employees from Havasupai reservations lands (Havasupai Tribe v Arizona Board of Regents and Therese Ann Markow 2008; Harmon 2010). Participants felt that the controversial research had gone beyond the description and intent of the original study as presented to them and consented to (Culture Clash on Consent [Editorial] 2010; Harmon 2010), and researchers had failed to anticipate culturally-based objections of the Havasupai people to certain research inquiries, findings and conclusions (Harmon 2010; Mello and Wolf 2010). Similar conflicts about informed consent processes and genetic studies of indigenous populations in other countries have begun to emerge (e.g., Munsterhjelm and Gilbert 2010).

As health studies make efforts to expand the cultural diversity of participant samples, it is not surprising that the potential for misunderstandings and conflict may be heightened and new challenges presented if agreement to participate is considered from the perspective of participants' understanding of research and the meaning of informed consent (Barata et al. 2006; Bhutta 2004). Informed consent strategies often are based on an "education model" (Dixon-Woods et al. 2007) with participants implicitly viewed as passive recipients of the information provided that, from the researcher's perspective, satisfies legal, scientific and ethical requirements (e.g., Beskow et al. 2001; Bhutta 2004; Marshall 2006). Alternatively, the informed consent process in culturally diverse populations can be thought of in terms of a "knowledge" model, with a focus on the meaning of participation to targeted individuals (e.g., Bhutta 2004; Dixon-Woods et al. 2007) and the *group's* assessment of additional risks and benefits of the study (e.g., Barata et al. 2006; Dawson and Kass 2005; Marshall 2006). This perspective emphasizes that cultural perspectives provide a system of meaning for an individual that guides the interpretation of events (Triandis 2000), sensitizing individuals to specific aspects of choice situations and affecting the persuasiveness of certain information (e.g., Buchtel and Norenzayan 2008; Di Maggio 1997; Hornikx and Hoeken 2007; Kamenstein 1996; Vaughan and Tinker 2009). Traditional approaches to informed consent may not be sufficient to address these issues without further consideration of what matters to individuals and is essential for meaningful decision-making about the risks and benefits of participation. Without an integration of a culture and diversity framework into planning and decisions regarding research protocols for recruitment and informed consent across diverse populations, some ethical issues are likely to remain unaddressed (e.g., Mello and Wolf 2010; Thorne 1980).

There are significant gaps in the current body of research on cultural diversity and informed consent in the United States. One major limitation follows from the fact that most studies on this topic have focused on comparisons between populations in industrialized and less industrialized nations (e.g., Bhutta 2004; Dawson and Kass 2005; Rivera et al. 2007) and this emphasis does not address the implications for population-based research of diverse groups (e.g., Marshall 2006) *within* many industrialized countries, including the United States (e.g., Fearon 2003). Within-country variability in cultural beliefs, expectations, trust and concerns about research is likely (e.g., Barata et al. 2006). Furthermore, sizable recent immigrant populations in the United States require consideration of the information needs of these cultural groups and communities whose participation in biomedical and genetic research is desirable and necessary for scientific, ethical, health and social reasons (Barata et al. 2006; James, et al. 2008). A deeper understanding of culture, diversity and the impact on research is needed to identify gaps in research protocols and anticipate potential challenges to the promise of informed consent associated with increasing diversity in research samples. This viewpoint is well represented in the traditions and literature of community psychology (Kral et al. 2011; Tebes 2010; Trickett 2009). As Cohen (2009) proposed, there are different forms of culture (e.g., religion, socioeconomic status, region of the country) and these may further expand within-country variability in perspectives on research. Community psychology has long emphasized the influence of culture and context on psychological processes (Kral et al. 2011; Tebes 2010), and in discussions addressing the application of psychological interventions to diverse communities, researchers (e.g., Trickett 2009; Barrera et al. 2011; Lakes et al. 2006) have argued that it is critical to understand the target recipients' culture before implementing interventions and to consider the recipients' acceptance of the intervention, as well as possible adaptations based on cultural differences. We propose that in a similar manner, researchers should first seek to understand target participants' culture (in multiple forms) when attempting to engage them in research and should design and implement an informed consent process that is responsive to the needs and preferences of prospective participants. From this perspective, researchers would be "putting culture front and center" as described by Kral et al. (2011) which should in turn

strengthen the shared understanding between participants and researchers, increasing the validity of the informed consent process.

A second limitation of the current literature on cultural diversity and informed consent is the frequent failure to conceptualize the act of providing informed consent as an example of a judgment or decision-making process involving the interpretation of and response to risk/benefit information and relevant communications (e.g., Dixon-Woods et al. 2007; Marshall 2006). The types of reasoning strategies and judgments that are assumed to be a part of the informed consent process are similar to decisions in other domains where people must interpret and weigh risk/benefit information to arrive at a decision (e.g., Di Maggio 1997; Vaughan and Tinker 2009; Weber and Hsee 2000). Relevant cognitive, motivational and affective processes involved in decision-making about risk acceptability can be greatly influenced by cultural values and past experiences (e.g., Boholm 2003; Buchtel and Norenzayan 2008; Weber and Hsee 2000). People will make sense of the research process and what is being asked of them based not only on information provided by researchers, but also on their beliefs, values and expectations that they bring to a setting (e.g., Cohen 2009; Kral et al. 2011; Thorne 1980). Understanding diverse participants' perspectives on the research process and the values, considerations, reasoning styles and other psychological or social processes that play a role in decision-making should be a primary determinant of whether the informed consent communication process is culturally appropriate (Barata et al. 2006; Bhutta 2004; Woodson and Karim 2005). These considerations are especially important for long-term population-based genetic studies where stored biosamples collected for one purpose may be used in the future for a different research question (e.g., Trinidad et al. 2010). Conflicts can emerge when cultural sensitivities to a new research agenda and findings were unanticipated and unknown at the time of original consent (e.g., Mello and Wolf 2010). In this way, longitudinal genetic and environmental studies on children's health present similar ethical dilemmas for informed consent as Thorne (1980) described for ethnographic research where the open-ended nature of fieldwork could lead to evolving research directions and analytical frameworks that were not explicit at the time of original informed consent.

Research that expands our understanding of the range of perspectives on these issues can produce insights regarding how to improve informed consent strategies and recruitment for socially and culturally diverse communities. The relationship between recruitment (gaining access to diverse communities) and informed consent procedures is complex and information presented at the time of recruitment begins the informed consent process (Thorne 1980). It is during this phase that the framing of the study's purpose and goals is first presented and potential participants' initial understanding of the research endeavor revealed (Culture Clash on Consent [Editorial] 2010; Thorne 1980). Variability in perspectives on specific issues regarding informed consent may be present at the recruitment stage and present ethical and practical methodological concerns, including how we educate communities about the research process, build trust between researchers and culturally diverse communities, and address expectations about the conduct of research, including the provision of results to participants. For this investigation, we explored the implications of conceptualizing issues of culture, diversity and the informed consent process from an "ecological" perspective as described in the community psychology literature (e.g., Kral et al. 2011; Tebes 2010; Thorne 1980; Trickett 2009). Consent to participate in research was conceptualized as a decision-making activity that occurs within the cultural and social contexts of potential participants' lives.

In this manuscript, we report results from a study we designed in preparation for recruitment for the NCS in Orange County, CA, a region of the United States where 41% of families speak a language other than English at home (U.S. Census Bureau 2010). Our Vanguard

Center for the NCS was one of seven initial centers selected to pilot the methods for the NCS, and the first author of this manuscript designed the present study, with contributions from co-investigators, as a formative study to gather information that could be used to better understand local communities and to develop strategies for engaging these diverse communities in the NCS. We obtained approval for this study from both the National Institutes of Health program office for the NCS and the federal Office of Management and Budget (OMB). Our study aims were to describe the experiences, perceptions, attitudes and values that are brought to bear when individuals from different racial or ethnic, socioeconomic and cultural backgrounds consider participating in biomedical research and to explore the themes that foster or diminish trust in researchers and institutions, and have implications for the informed consent process. We expected this formative research phase would reveal that participation rates are affected in part by bioethical concerns related to informed consent, trust, return of results, and the appropriateness of strategies used to inform or educate communities about research studies. To narrow the focus of this manuscript, we report only those results related to the following aims: to explore the informed consent process and participation decisions within culturally and socioeconomically diverse communities; to examine whether standard assumptions of the informed consent process are equally valid in different cultural contexts or life circumstances; and to identify the range of responses of diverse individuals based on experiences, perceptions, attitudes, values, and preferences that ultimately will affect research participation and consent rates. More generally, the study sought to examine how culture may shape, influence and frame issues of informed consent in diverse communities, and to identify “what matters” to different individuals and communities to make an informed decision about participating in the NCS.

## Method

### Participants

To reflect the demographic characteristics of Orange County, CA, we recruited Asian American, Middle Eastern, Latina, and White/European-American women ages 18–49 through neighborhood advisory committees (NACs) established as part of NCS outreach activities in our area. NACs, a component of a broader community outreach and engagement strategy for our study center, were designed to serve as a mechanism for ongoing bidirectional communication between investigators and community stakeholders (volunteer NAC members) in the geographically defined communities selected for participation in the NCS. NAC members included neighborhood residents, school personnel, social service agency representatives, and other community members. NACs worked with investigators to develop community-specific outreach and engagement strategies for the NCS. For this research, NAC members distributed recruitment flyers through community-based organizations, schools, and libraries. Fifty-three women (Table 1) volunteered to participate in focus groups held in cities with diverse sociodemographic profiles (Table 2).

### Procedure

The University of California, Irvine, Institutional Review Board approved this study. Women who responded to recruitment flyers called our study center to register for the focus groups. Research personnel read a study information sheet to participants over the phone prior to registering the participant and obtained verbal consent; the study information sheet included basic information, such as the description of the study, time commitment (90 min), anonymity, and compensation (\$35 cash). At the start of each focus group, the facilitator distributed the same study information sheet to participants, reviewed the information, provided an opportunity for questions, and then asked for verbal consent to proceed with the focus groups.

We used focus groups as a research strategy because they provide a time-efficient means for gathering comprehensive data on beliefs and values on specific topics, and enable researchers to observe how opinions coalesce or diverge (Hill et al. 1997; Morgan 1998). This qualitative technique also reflects an idiographic approach where the meaning of research participation and the implications for informed consent process are explored within the contexts of individuals' lives and circumstances (Kral et al. 2011). We developed a focus group guide that began with a description of the NCS derived from informed consent documents (e.g., purpose and length of study, risks, benefits, types of data to be collected):

We've asked you here tonight because the information that you can provide will be a very important part of our preparation to conduct the National Children's Study in Orange County. We need your input and want you to share with us your honest and candid thoughts. Every opinion is equally important. Together the information you give us will help us better understand what we will need to do to encourage communities and individuals to be a part of (or participate in) the National Children's Study.

Let me give you a brief background on the National Children's Study before we begin. Children and families today are facing serious challenges to health and wellbeing that include asthma, infant mortality, obesity, diabetes, learning disabilities, and injuries. The purpose of the National Children's Study is to help us understand how the environment affects children's health, growth, and development. We are also interested in how the environment might affect children differently depending on what they inherit or other individual characteristics. Knowing more about this eventually could help us to prevent disease and promote health. This study will involve 100,000 children and families followed over the course of 21 years. Those 100,000 families are in communities all across the United States. In Orange County, 1,250 children and families will be involved. The study will involve a large, representative sample of the nation's children, which means that it will include children from all income, racial and ethnic groups. 15 neighborhoods in Orange County have been selected by chance to be included in the study. We will be asking all adult women who live in those 15 neighborhoods to participate in the early part of the study, and we will ask the women who end up having a baby during the next 5 years to enroll themselves and their babies in the full study. In spite of the fact that ALL communities and parents care deeply for the health and wellbeing of their children, when we ask women in the selected neighborhoods to participate, there will be some who will enthusiastically agree to participate and some who will not. We want to better understand the reasons that make people more likely to participate and the concerns that might cause them to hesitate or decide not to participate at all.

We have prepared a few questions to help guide our discussion. We will ask each of you to respond to the questions and to share your thoughts. Our goal is not to reach agreement among all of you on issues, but rather to identify the range of opinions and ideas on an issue. There are no right or wrong answers. We encourage you to offer your thoughts and opinions even if they are different from what someone else has said. Also, we want to make sure we accurately represent all of your opinions and thoughts, and so with your permission, we will tape record and transcribe our session. Individuals will not be identified in the transcription.

After reviewing some standard procedural guidelines for focus groups, the moderator provided more detail on the National Children Study recruitment and data collection components:



We will be asking women in selected neighborhoods to participate in this study. If she joins the study, we will schedule visits with her, her child, and the child's father (if she agrees) to collect information for the study. There will be about 15 total visits spread out over the 21 years. The information we collect at visits may vary, but will include interviews, ultrasounds, blood samples, and samples from the environment, such as dust in the home. The initial visits will be at her home during her first 12 weeks of pregnancy. Two other visits during the course of her pregnancy will be at the clinic. When she gives birth, we will coordinate with her doctor to visit her and her baby in the hospital to get information about the birth and to examine and take pictures of the child. When the baby is 6 months old and 12 months old, we will make another home visit. When the baby gets older, there will be about 1 visit every 2–3 years. Each visit will probably last about two to 3 h and be conducted either at home or at a clinic. Between scheduled visits, we will contact the mother from time to time. There will be no costs to the participants for their participation in the study, and they will receive some compensation for their time. Now that you understand the basics about what participating in the study will entail, we would like to know how you would initially respond if you were invited to participate.

Moderators asked seven main questions with additional probes for certain questions. To capture the participant's initial reaction, our first question was, "As I described the study for you, what thoughts first came to mind?" We also asked questions designed to identify a range of information needs and decision styles, such as, "What information would you need to see or receive before making a decision to participate?" We asked questions regarding who might be involved in a person's decision-making process: "Who would you talk to and ask for advice when considering whether or not to participate in the National Children's study?" Moderators specifically asked about the potential involvement of family members in decision-making: "Families make decisions in different ways. Some people in families make decisions themselves, sometime one person makes all the decisions, and some families make decisions together. When approached and asked to participate, who in your family needs to be involved in the decision-making?" Other more narrowly focused questions addressed reactions to and any concerns about the type of information the NCS would generate and beliefs about the information that would be most useful to make the decision to participate or not: "Are there certain details about the study that would be most important to your decision to participate? For your most important concerns, what could we do to address those concerns in a way that would make you feel more comfortable about participating?"

Moderators and assistants completed training in qualitative research techniques and focus group methods directed by an experienced scientist with expertise in qualitative research methods. Training included a review of and practice in strategies for conducting effective focus groups, such as how to elicit involvement in the group discussion from all members and how to respond to challenging group dynamics. Moderators and assistants participated in mock focus groups, where they practiced their skills using the study guide and received immediate verbal feedback from the trainer. Mock groups were videotaped and later viewed and analyzed in another training session. Four moderators were trained, and one was a native Spanish-speaker. Moderators conducted 90-min focus groups in community locations (e.g., schools, libraries), and sessions were audio-recorded and transcribed verbatim (Stewart et al. 2007; Fern 2001). Spanish transcripts were translated into English before analysis.

## Analyses

Transcripts were analyzed using qualitative thematic methods (King 1998; Crabtree and Miller 1999), which is a technique between the extremes of content analysis (in which codes are pre-determined and analyzed statistically) and grounded theory (in which no codes are

defined a priori). The thematic analysis began by having investigators read the first focus group transcript together and develop an initial coding scheme based on the questions in the focus group guide and the discussion during the session (Hsieh and Shannon 2005). Codes were generated from categories that arose from within the data and based on relevant literature (Bogdan and Biklen 1998; Ayers et al. 2003). Three investigators independently coded the transcripts and then reviewed and discussed their codes to achieve consensus. Ideas and concepts that were communicated through extended passages and exchanges among participants or complete responses were also coded. There was high reliability in coding among the three investigators, with 95–99% agreement for all groups.

## Results

### Theme 1: Participants Self-identified as Members of a Cultural Group or Community When Discussing Their Potential Participation in Research

Many participants, particularly in more ethnically or culturally diverse groups, began some of their responses regarding research participation decisions and concerns with a reference to a group or community: “As an Iranian, there will be a lot of questions and suspicion and hesitation...” [in response to the question, “What would your initial reaction be if invited to participate in the NCS?”]. Some references to membership in a particular community were made in the context of discussing the influence other family and community members could have on an individual’s decision to participate in a research study. In a Latina group, one participant suggested that focus group participants could form a “fight that will convince” the community to participate in the NCS, illustrating the impact a community collaborative effort could have on recruitment. Participants also noted that community members, particularly elders and grandparents, could prevent another member of the community from participating: “If you reach the older generation, I think there will be barriers to even encourage them to participate in the study,” subsequently describing how those barriers would be communicated to the younger generation who likely would not participate without the support of the elders. In several instances, participants noted that acculturation may affect the degree to which community or group influence affects an individual’s decision. For example, one participant stated, “You will always trust your—I’m very Americanized, so I’m not really that way, but my mother, if another Filipino person were to tell her to take this particular vitamin, she would go out to the store to buy that vitamin.” Most of the references were to membership in ethnic communities and sub-communities within a particular ethnicity, but participants also made statements identifying themselves with religious communities or as members of a socioeconomic group, often by beginning their responses with “we” (e.g., “...We have different concerns than people in the less affluent area would”).

### Theme 2: Ease of Participation may Differ Between Communities

Across all focus groups, participants raised issues that would affect the ease of participation in their communities. Participants residing in higher income communities commented that it would be easier for their community to participate in contrast to other, more socioeconomically disadvantaged communities.

*Participant:* I think that it would be an easier decision for this group than it would be, say, for the [socioeconomically disadvantaged community]...I think that we are less likely to be concerned with the day-to-day things. Like how am I going to put...how am I going to keep my kid out of a gang? ...I just think we have more time to think about these things than people who might be in a less socioeconomic advantaged area. I mean, being realistic, not being any kind of prejudice or anything aside – but we have different concerns than people in the less affluent area would.

**Certain characteristics of immigrant populations may impact willingness to participate**—Some of the characteristics of immigrant populations that were identified as potential barriers to participation included concerns about immigration status (e.g., for undocumented residents there might be concerns regarding potential consequences associated with participation). In some local communities there are many residents who come to the United States on temporary work visas and stay fewer than 5 years; participants stated that their status as temporary residents might impact willingness to participate.

*Participant:* ...there's a lot of immigrants here who are not sure they're moving, if they're going to stay. Especially in Korean communities... They're here for a short time—5 years, 3 years. So a question will come out, I think, of most of the immigrant community: What if I leave in 3 years? Or I'm not sure I will be here? This is another barrier that you're going to hit.

### Theme 3: Perceived Risks Associated with Participation

**Emotional risks**—One participant expressed concern that the data collector might “judge” her parenting based on her responses. Another participant stated that she did not “want to be objectified by questionnaires or formal interviews.” Participants in all groups discussed the possibility of receiving adverse test results, especially results of genetic testing, as an emotional risk. There was disagreement among participants regarding whether or not they would want to be notified of adverse results and whether receiving these results constituted a risk (or benefit) of participation.

*Participant 1:* ...the baby, with his blood sample, you would be able to tell if he's becoming unhealthy or healthy. What happens when you tell someone, “You know what? Your baby is unhealthy, what -” (interrupted by participant statement below)

*Participant 2:* People are going to become scared... for many people that can be traumatizing.

Another emotional risk identified by some participants was embarrassment resulting from researchers taking body measurements. In addition, participants described how participation during early pregnancy could increase the emotional impact of pregnancy loss. There was strong group agreement with the following statement:

*Participant:* What if there is a pregnancy loss? How is that handled? Cause I would think that you are involved in this study – just the knowledge that you are involved in this study – if something goes wrong in the pregnancy, it could have more of an emotional impact... I think because if you are expecting everything to go OK, and you think you are going to have a child, and you are enrolled, it is almost like having a crib already....

Participants felt that if questions were asked following the pregnancy loss, this could increase the emotional impact: “Well, like, will there be questions? You know, did something happen? Did you fall down?”

**Potential risks associated with privacy and security**—Participants expressed concern regarding the security of their information, as well as some skepticism regarding how researchers could keep information secure over 21 years. Some participants expressed concern about the governmental involvement in the NCS and how it would affect their privacy. In addition, participants wanted to know what steps would be taken to prevent the misuse of data.

**Intrusiveness or interference**—Many of the perceived risks of participation related to potential intrusiveness or interference in personal lives. For example, participants expressed

fears that the NCS might try to change or interfere with child-rearing practices. Some participants also viewed research visits in the hospital at the time of birth as intrusive: “I know that a lot of people seem to treasure that time for family and they may resent that particular time in the hospital being set aside for a study or whatever.”

To lessen the perceived intrusiveness of the birth visit, participants recommended having as much information filled out ahead of time, having their doctors collect the samples for the research team, keeping the visit short, and minimizing intrusiveness. There was strong group agreement with the following participant statement: “As long as they [the birth team] could stay in the background and not involve themselves, or with the family...I think it would be handled discreetly, then it would be fine.”

Some participants, particularly those recruited in higher income areas, expressed concern over the collection of the cord blood, and indicated that they wanted to have this collected and banked for possible personal future use. Participants also asked if they would have access in the future to cord blood if it was collected and stored by the researchers.

**Adverse effects of participation on insurance coverage**—Participants also expressed concern that their child’s participation would lead to diagnoses or test results that might be discovered by insurance companies that could potentially deny coverage or treatment. One participant asked, “So the insurance company can’t come back and sue you, if you, you know, legally knew about something?”

**Anticipated conflicts between cultural values and the research process**—Participants described concerns about how participation might conflict with their cultural traditions, particularly traditions of not discussing children’s problems or pregnancy with those outside of one’s family.

*Participant 1:* I am Iranian American... Basically, in my background, it’s a hush-hush thing, and we don’t like to talk about it if our kid has some sort of an issue.

*Participant 2:* ... Korean people don’t really want to speak out about their children’s problems.

*Participant 3:* In terms of pregnancies, Koreans are extremely cautious about their pregnancy, especially for the first trimester so they don’t want to even talk about their pregnancy to their family until they make sure everything is OK...

**Blood draws**—Some participants indicated that having blood drawn during a home visit involved risk and stated that they would be more comfortable if this type of procedure were done in a clinic or hospital. Many participants expressed reluctance to agree to blood draws for their child, emphasizing the discomfort and pain the child would experience; for example, a participant stated “...as long as there is no ... extra blood tests that a child has to go through. To get a 2 year old to sit there and do that is like torture. You know that would be a concern.”

**Other perceived risks**—Other perceived risks were described by participants and some varied by group (Table 3). For example, Latina women expressed concerns about potential detection for immigrants who are not documented, as well as concern about being one of the first participants in an “experiment.”

#### Theme 4: Concerns Related to Participant Burden

Participants expressed concerns about study procedures including the length of the study, length and number of visits, and convenience of scheduling. Some participants believed that

concerns about the length of the study could be addressed by letting participants know that they could withdraw at any time.

*Participant:* If you could put, ‘if you wish to continue.’ Cause then they don’t feel like, ‘Oh my god, 21 years.’ It’s like, ‘OK, I could do five. I could do elementary school.’

Other participants, particularly Asian-American women, were concerned that if a person felt a strong sense of obligation to continue, simply stating in the consent that you may withdraw would not be enough to ease concerns regarding a 21-year commitment.

**Burden of study visits**—Participants expressed concern about the time and convenience of study visits, raising concerns about missing work or school. Some participants preferred a greater number of shorter visits, and others preferred fewer, longer visits. They recommended that researchers provide options, both in terms of the visit schedule (length and number of visits) as well as the visit format (e.g., telephone, internet). They also recommended providing reimbursement for travel and childcare costs.

Some participants viewed travel to clinic visits as a burden, but others felt that if the visits were not too frequent, they would not be a barrier to participation. Participants also mentioned that “hosting” researchers during a home visit may be a burden, and there was strong agreement that there would be a perceived need to prepare for the researcher’s visit, particularly in focus groups conducted in areas of high socioeconomic status, as illustrated by the discussion between the following three participants:

*Participant 1:* Having to welcome someone into your home...

*Participant 2:* Yeah, you have to change. You have to get presentable!

*Participant 3:* I would clean. All pregnant and trying to clean!

### **Theme 5: Perceived Benefits Associated with Participation**

Participants in all focus groups identified societal benefits (e.g., identifying the causes of child health problems, improving the health and welfare of children for generations to come), as well as perceived personal benefits associated with participation in the NCS. Expected personal benefits included receiving feedback on their child’s health and development, environmental testing results, financial incentives, ultrasounds, and answers to questions about children’s health. For example, a participant stated: “Obviously the two motivating factors would be involved: getting the results, and also the compensation ... Especially stay at home moms where money is really tight.”

During some focus groups, particularly with Latinas, participants expressed an assumption that results would be used to develop programs and services that would help children. These participants also expected that their personal physician would be actively participating in the study, and their perspective on the NCS did not reflect a separation of participation in research from routine medical care activities associated with pregnancy and childbirth.

Another cultural difference was noted in the importance ascribed to receiving particular results: in focus groups conducted in higher socioeconomic areas, child evaluation results were viewed as interesting, but not necessary (a “second opinion” because they were already receiving medical and other care that would provide similar results) and environmental results (e.g., testing for mold in the house) were viewed as very important as they were not as accessible. In lower socioeconomic areas, child evaluation results were seen as extremely important and there was little, if any, discussion regarding environmental results.

## Theme 6: Information Needed to Make a Decision

**What is the meaning of participation?**—An overarching theme that emerged across focus groups was the importance of knowing what participation would mean to the individual and her child. One participant stated: “Well, I might be wanting to participate in this study if I know exactly what the meaning of participating means.” Some cultural differences noted in interpretations of what research participation means are summarized in Table 3. For example, Latina participants described expectations of research participation (e.g., receiving guidance on child-rearing) that were similar to expectations one might have of a social service program. The comparison was so strong that the participants stated that having access to this “intervention” would be important to the future of their child and reason enough to enroll in the study:

*Participant:* If you would specify that we are not going to transform your child, we are not going to make him our way, we are only going to guide him and avoid so many errors that have consequences in the future. These, I think, are your intentions to help guide our children, good food, good education, well taken care of, and, well at times we don't have the guidance of our mothers, sisters, or anyone, and so then we do things like a crazy person. I do not think there will any [barriers to participation] there.

Across focus groups, participants expressed a need for detailed information during the informed consent process, such as a detailed outline of study visits and details about the types of research that would be conducted with their samples. Participants recommended that information should be presented “professionally” to increase legitimacy (e.g., brochures, frequently asked questions and answers, and a DVD introduction to the study), and that materials emphasize the individual's freedom to choose to participate and the benefits of the study. One participant stated, “Throughout the time they're sitting there stressing about, you know, something, just bring it back home to, you know, this will help kids just like, you know, just like your daughter and son. I think every mother in humanity would understand.” Cultural differences were also noted (see Table 3 for examples).

## Theme 7: Decision-Making Strategies

**Risk–benefit analyses**—Some participants described their decision-making process using what could be categorized as a “risk–benefit” analysis. They weighed personal or societal benefits against the discomforts of participation (providing biological samples, time, convenience). Notably, some of the perceived benefits of participation were not those explicitly mentioned in a description of the study but were assumptions that followed from individuals' interpretation of the research process.

*Participant:* I just think, like, it's no big deal. Like, 20 years from now you can save some child from having autism and suffering through all this therapy and, or having diabetes early on. It's like a little blood test, or going to the hospital. For me, you know, if somebody would have done it for me 20 years ago, and my child wouldn't have to go through something then, you know, I wouldn't think that that's a major deal for me.

**The decision to participate is a social process**—Across groups, participants described the decision to participate as a social process, although cultural groups differed in the extent to which this perspective was expressed and in ideas about who would be involved in that process. Some participants stated that they would discuss their decision with their husband or baby's father, although there were differences in the weight given to his opinion.

*Participant 1:* I would probably make the decision and then talk to my husband about it. See if he was comfortable. I mean, it would ultimately be my say, though. Being that I'm probably the one doing most of the work.

*Participant 2:* It would definitely be a joint decision between the two of us. Cause if he really didn't want me to do it, then, you know, I wouldn't want to do it then.

Some participants stated that they would discuss their decision with older generations in their families and indicated that the older generation could facilitate or hinder recruitment. This perspective was especially prevalent among women of Middle Eastern and Asian backgrounds. Participants in all groups stated that they would discuss their decision with someone in their social circle (including internet-based social circles) and that they'd be influenced if a member of their community urged them to participate.

*Participant:* But if you approach me, I'd say, 'Oh, you know what? Let me think about it.' But if she [an older mother from the community] said [in reference to a member of the research team], 'You know what? She's fine. She's got a great program.' It's more or less the other parents within this group... that's going to trust each other more than anybody else.

Some participants indicated that they would discuss their decision to participate with personal physicians. However, there was disagreement among participants about the degree to which their physician's opinion would impact their decision. For some, they would seek and give substantial weight to their personal physician's view of the study when making the decision to participate as illustrated by a participant who stated: "I'd want to know that my doctor was OK with it. I would definitely run that by them to make sure the hospitals locally or doctors working with different women are aware of it. If my doctor said that it sounds sketchy, I'm not going to do it."

**Using family meetings in the recruitment process**—Participants recommended family meetings (including spouses and for some cultures grandparents) where researchers could describe the study and allow each member of the family to hear directly from the researcher. Women in all focus groups emphasized the importance of engaging fathers, noting that this would be necessary for retention.

**The decision to participate is a process that will occur over time and will be impacted by trust and the relationship between participants and researchers**—Participants also indicated that their decision would not be immediate but would develop over time as trust builds and a relationship with the researcher strengthens. This was particularly emphasized among Latina focus group participants.

## Discussion

Large ongoing or planned population-based longitudinal biomedical and genetic studies of health invest considerable resources to improve the representativeness or cultural and ethnic diversity of research populations. Such diversity contributes to significant progress in understanding genetic-environment interactions and relative genetic contributions to health and a variety of disease conditions across varied populations (e.g., Rotimi and Marshall 2010). However, this increased diversity raises questions about traditional approaches to informed consent and whether these strategies are adequate to achieve ethical requirements and standards if the process is considered in isolation of the cultural and social processes that influence individuals' decision-making about research participation (Mello and Wolf 2010; Thorne 1980). Our results provide a rich profile of cultural similarities and differences in perspectives on informed consent and decision-making regarding participation in the NCS, and challenge traditional assumptions of the informed consent process in culturally

diverse populations. This study also revealed a range of information needs within communities regarding recruitment and potential barriers to participation, and how these findings are linked to informed consent issues. As others have noted, knowledge about potential participants' perceptions of and expectations for research participation, including risks and benefits, is essential to develop an informed consent process that can minimize subsequent misunderstandings, perceived violation of trust and other difficulties between individual participants, communities and researchers (e.g., Dixon-Woods et al. 2007; Harmon 2010; Levy et al. 2010; Woodsong and Karim 2005). Providing informed consent after weighing a study's risks and benefits in the context of a research setting may share characteristics with other decision tasks that involve judgments about the acceptability of risks and are known to be influenced by a person's cultural values, social or past experiences and prior beliefs (e.g., Kreuter and Haughton 2006; Kreuter and McClure 2004; Nisbett et al. 2001). Perspectives from community and social psychology on culture, diversity and psychological processes involved in decision-making provide a framework to systematically consider the multiple ways in which culture may influence reasoning about and expectations for participation in a biomedical study (e.g., Kral et al. 2011; Trickett 2009). Principles, discoveries and conceptual frameworks from community and social psychology and other behavioral sciences increasingly are used to inform biomedical and public health researchers about the ethical and practical issues of conducting research in communities that may not have extensive prior experience with formal research studies and may have concerns and perspectives that differ from those traditionally emphasized in informed consent protocols (Flicker et al. 2007; Godard et al. 2004; Jenkins 2010). Previous studies have demonstrated that individuals are active, rather than passive, recipients of the type of information that is provided about a research study (e.g., Hornikx and Hoeken 2007; Lehman et al. 2004; Yick 2007) and will bring to the research situation assumptions and expectations that may or may not be addressed in informed consent documents. Our research supported this view and revealed how individuals frequently described their consideration of participation in the NCS in reference to broader cultural values, beliefs and prior experiences (e.g., value of family input for decision-making, social norms against discussing pregnancy during the first trimester, understanding the research endeavor by reference to a medical or social service provision model). Moreover, as we describe below, our results challenge some apparent assumptions of the standard informed consent process: (1) the assumption that a thorough informed consent document will lead to a shared understanding between a participant and researcher; (2) the assumption that decisions are primarily or solely based on weighing the risks or burdens of research participation against anticipated benefits; (3) the assumption that decisions are made only at the individual level; and (4) the assumption that the description of research provided in the informed consent documents provides sufficient and appropriate information.

### **Does a Standard Informed Consent Form Ensure a Shared Perspective Between Researchers and Diverse Participants?**

The diverse participants in our study identified a range of perceived risks and benefits, expectations, and assumptions about the research process that would influence the decision to participate. Some, but not all of these, were anticipated by researchers and, therefore, already incorporated into consent forms. However, given the broad range of perspectives and concerns about these issues among diverse participants, it is unlikely that a single consent form alone could ensure a shared understanding. Individuals brought to discussions a set of assumptions about the research process based on prior experiences, values and life circumstances. Importantly, there were misconceptions and inferences expressed in several focus groups about the research process. For example, participants in all groups expressed the belief that there would be a societal benefit for participation in the NCS and also personal benefits, but consistently among Spanish-speaking participants, the expected



personal benefits exceeded what is feasible in or appropriate for the NCS. It is noteworthy that the expected benefits were associated with the expectation that participation in a research study would be similar to participation in a social service program and beliefs that these two endeavors shared key characteristics in terms of service delivery. Understanding the cultural and experiential basis of these inferences helps to understand the behavior of potential participants in this setting or context (Cohen 2009). This finding has implications for how we educate communities about research, but also highlights the importance of researchers identifying and addressing participant expectations during or prior to the informed consent process. This is consistent with prior cross-national and international studies that found cultural differences in expectations for benefits to be derived from research participation (e.g., Rivera et al. 2007), even though some assumed benefits were never mentioned explicitly during the informed consent process (e.g., Dawson and Kass 2005; Dixon-Woods et al. 2007). Researchers have found that for some cultural groups, expectations for the research process may not distinguish between a study that is strictly for research purposes and provides no direct benefits and one that will provide a “service” or medical care (e.g., Bhutta 2004; Rivera et al. 2007; Marshall 2006). This same perspective on the benefits of participation in biomedical research studies has been observed in cultural groups outside of the United States and may not be uncommon among communities that previously have not participated in and are less familiar with formal scientific investigations and protocols (e.g., Bhutta 2004). In fact, health and biomedical researchers involved in cross-national or international settings have recognized that the clarification of participation benefits among culturally diverse groups is a goal of informed consent that should have the highest priority (e.g., Dawson and Kass 2005; Rivera et al. 2007). Our results challenge the notion that a signed consent form documents shared understanding, and indicate the need for more education of both researchers and communities, and further interactive communications with participants to identify assumptions and clarify what participation means. In situations where there is a reasonable possibility of ongoing, culturally-based misunderstandings of the benefits and risks presented by a study, consented individuals’ understanding of the meaning of participation may need to be confirmed at a later date, and as some have suggested, a re-consent or a tiered consent approach may be warranted, particularly for longitudinal biomedical or genetic studies (e.g., Mello and Wolf 2010) where cultural differences are likely to exist in the stigma associated with certain types of genetic or genomic research and participation in these investigations (e.g., Murphy et al. 2009).

### **Do Participants Make Decisions by Weighing the Risks or Burdens Against Anticipated Individual or Societal Benefits?**

In contrast to the assumption that decision-making occurs as a result of an individual’s weighing of benefits against stated risks reflected in most current recruitment and informed consent procedures, participants’ discussions of whether to participate in a study like the NCS revealed multiple decision-making strategies, including but not limited to a risk-benefit analysis, social decision-making, and relational decision-making. Almost all participants indicated that the benefits outweighed the risks and “costs” of participation, although to minimize the burden of being a research participant, they recommended that researchers provide participants with many choices regarding the length of their participation, location of visits, and options for partial participation (so that they could opt out of certain procedures or study visits). These comments reflect an assumption and expectation of flexibility in the conduct of research and data collection activities that can be tailored to the life circumstances of participants, and that the burden (i.e., risks) of participation would be lessened by researchers’ adaptation as the study progresses. This is in contrast to a traditional principle of scientific inquiry that aims for standardization in procedures across participants to increase the reliability of data, and suggests one domain where researchers

and some participating communities may not initially have a shared understanding of the research enterprise. Some biomedical researchers have suggested the need for flexibility in informed consent and research procedures to accommodate the social and cultural contexts of a study (e.g., Barata et al. 2006; Dawson and Kass 2005). However, careful consideration is needed to balance flexibility with maintaining the scientific integrity of the study.

### **Are Decisions About Participation Individual Decisions?**

Our results challenge another underlying assumption of informed consent documents—namely, that the *individual* is deciding to participate and that risks and benefits will occur at the individual level. Most participants described social processes that would be part of decision-making, but the individuals identified as central in those social interactions varied across cultural groups. Within some communities, cultural values, norms and perspectives on social relations and the role of the family in decision-making may lead to deliberations about participation that are neither framed nor carried out at the level of the individual (e.g., Barata et al. 2006; Dawson and Kass 2005; Marshall 2006). A culturally sensitive study design should allow for social decision-making processes to occur within a reasonable timeframe. The importance of social relations for some individuals also was revealed by comments indicating that they would be more likely to participate if they had a trusting relationship with the researcher. Spanish-speaking participants, in particular, expressed a desire to have multiple visits with researchers so that they could build a relationship over time before consenting or deciding to participate.

Moreover, during group discussions, participants referred to themselves as part of a larger group or community when considering participation in and the risks and benefits of the NCS. This finding raises a question that recently has been discussed in regard to informed consent protocols and human subject protections (e.g., Ross et al. 2010). Risks or harm from participation in a research study can occur at the level of an individual, but also at the level of a community or group (Ross et al. 2010), as illustrated in the case of the dispute about informed consent between the Havasupai community and university researchers (Mello and Wolf 2010; “Culture Clash on consent,” 2010; Harmon 2010; Legal notes 2010). Traditionally, most informed consent procedures consider the individual as a free and independent agent and assess possible harms solely to the individual as an autonomous agent (Flicker et al. 2007; Woodsong and Karim 2005). However, as more culturally diverse communities and individuals are brought into the research process it may be useful to consider whether strong cultural orientations toward valuing collective or group agency vs. personal agency (e.g., Lehman et al. 2004), and strongly identifying the self in relation to others vs. an independent self (e.g., Bandura 2002), will predict different ethical concerns about the informed consent process in terms of potential harms at the level of communities or groups (e.g., Cohen 2009; Flicker et al. 2007; Ross et al. 2010).

### **Does the Description of Research Provided in Informed Consent Documents Provide Sufficient and Appropriate Information?**

National and international ethics guidelines for informed consent require that participants are provided with meaningful, culturally appropriate, adequate, clear and accurate information about the purposes, risk, benefits, procedures, disposition of data and rights of the individual (e.g., Beskow et al. 2001; Dawson and Kass 2005; Rivera et al. 2007; U.S. Code of Federal Regulations 2009). Our results confirmed that participants desire detailed information about what participation involves, although the details emphasized varied across groups. Before consenting, participants asked for interactions with knowledgeable research staff who could explain why biosamples were necessary and what would be done with them. These themes highlight the fact that the disposition of biosamples is a significant concern not only for recruitment and participation but also for ongoing informed consent. Other

researchers and ethicists have commented that the open-ended and indeterminate future use of these samples for additional research raises questions about original consent and have suggested alternative more flexible tiered informed consent strategies (e.g., Levy et al. 2010). However, these also should be informed by a consideration of the cultural and social processes that may influence whether an individual truly feels “free” to refuse to provide consent for some of the research options provided on a standardized form. Participants in this study also recommended that researchers provide forums for the exchange of information where questions about the study could be answered. In Spanish-speaking groups, participants described this process as similar to a town hall meeting or community party; for participants recruited from more affluent, predominantly European-American communities, participants described this as occurring via a Facebook page or “webinars.” An additional question about the adequacy of informed consent procedures was raised by findings that among Asian Americans, simply stating that one could withdraw from the study during a consent process did not address concerns about commitment, due to strong cultural values that give high priority to maintaining one’s commitments. This suggests that more reassurances—beyond the standard informed consent language about the voluntary nature of continued participation—may be needed. These findings challenge some assumptions of the informed consent process as now practiced, and have implications for the methods used in diverse communities to obtain informed consent. The informed consent and research education process must be designed to be compatible with the local cultural and social contexts of the proposed project (Barata et al. 2006; Dawson and Kass 2005; Kral et al. 2011; Woodsong and Karim 2005), and our results suggest that to adequately inform diverse individuals and communities, researchers should consider going beyond the minimal step of disclosing basic information about the research in a consent form.

## Implications for Researchers

We encourage researchers to strive for genuinely *informed* consent and to consider taking steps beyond the minimal requirements for regulatory approval of research protocols when designing their studies. As Thorne (1980) predicted, “getting a signed consent form has become an opening ritual” (p. 289) and there is a risk that researchers will become overly reliant on a standardized initial consent form and will fail to consider the need for additional education, ongoing communication and consent, and the social nature of decisions to participate in research. We agree with Thorne, who stated:

While the principle of informed consent in some ways seems appealing because it is absolute and hence apparently an ideal for all circumstances, that is precisely one of its limitations. In its abstract individualism, the vision is narrow; it ignores historical and social contexts and questions about the purpose of knowledge. By itself, the doctrine of informed consent does not do full justice to the complexity of the ethical judgments fieldworkers confront. (p. 294)

As our data illustrate and other researchers have suggested (e.g., Dawson and Kass 2005), there are limitations of the individual-level model of informed consent and cultural, social and other contextual factors are important for decisions regarding research participation. The risks from participation in some subpopulations may be at the level of the community or group, and the informed consent process should include a preliminary procedure to explore this possibility for the particular cultural and social groups who are targeted for participation in a planned study. To facilitate the development of more culturally sensitive plans to recruit and obtain consent from diverse communities and individuals, we suggest that researchers or those who review research (e.g., grant proposal reviewers or institutional review board members) consider asking these questions when reviewing study plans to obtain informed consent:

- Have the researchers taken steps to understand the cultural and social contexts (including contextual factors related to race or ethnicity, language, socioeconomic status, immigration status, educational level, religion, gender, etc.) of their targeted participants that may affect interpretation or meaning of the research and informed consent process? Is that understanding reflected in plans to obtain consent for the proposed research? This understanding could be achieved in part by the examination of existing scientific literature and empirical studies on culture, diversity and informed consent that relates directly to targeted populations or communities.
- Have researchers taken steps to build trusting relationships with participants or communities, or does their recruitment plan includes steps they will take to do so?
- Does the proposed informed consent plan encourage ongoing informed consent throughout the research process rather than simply relying on the initial consent form?
- Does the informed consent process incorporate methods of educating participants about the research process that are appropriate for that particular group of participants? (e.g., oral presentations, videos showing research procedures, etc.)
- Have the researchers considered the applicability of community or family consent as an additional step preceding individual consent?
- Has the process for informed consent (including consent forms, educational materials) been shaped by community collaboration, consultation and/or pre-tested with or reviewed by community members? Has their feedback been used to improve the process or materials? In particular, have community members been asked to identify potential risks not considered by researchers or potential assumptions (e.g., possible benefits) that should be addressed during the research education or informed consent process? Have researchers considered how increasing cultural, experiential and social diversity in participant populations could lead to additional or unexpected emotional and other risks (e.g., social stigma associated with some research results because of cultural values, traditions and beliefs) that may differ across diverse groups?
- When determining research procedures, have researchers built into the protocol reasonable accommodations or modifications that will increase access to participation for participants from underrepresented communities?

## Conclusion

Efforts to increase the cultural, social and ethnic diversity of participants in population-based biomedical and genetic research necessitate a reconsideration of the adequacy of traditional informed consent processes and materials. Our data illustrate the complexities involved in establishing a shared understanding between researchers and participants about the meaning and nature of studies and supports our argument that researchers should provide a culturally responsive process for decision-making. For individuals who come to research studies with different expectations, cultural values and understandings of research, communications during informed consent should aim to clarify, identify and correct, if necessary, expectations and assumptions about study procedures, risks or benefits, but also educate investigators about communities they hope to engage in the research. Furthermore, informed consent protocols should address the range of concerns and perspectives that guide decision-making about participation for individuals from diverse social and cultural backgrounds (Barata et al. 2006; Levy et al. 2010). Failure to do so early in the research process can result in a host of unintentional consequences including lower participation and

retention rates, erosion of trust between communities and researchers, inadvertent violation of ethics principles for biomedical and genetic research, and decreased validity of the study (e.g., Bhutta 2004; Levy et al. 2010; Marshall 2006). Social and cultural contexts and past experiences influence expectations for and interpretations of “informed consent” (e.g., Dixon-Woods et al. 2007; Marshall 2006; Thorne 1980), and additional research is needed to identify the full implications of these contexts for the informed consent process. Findings from this study and others that describe apparent differences in beliefs about or expectations for scientific research for individuals from different cultural and social backgrounds (e.g., Marshall 2006) can provide guidance to large population-based studies that are intended to reflect the ethnic diversity of the entire society. More research is needed to examine these issues with other cultural groups, as well as with men given that only women participated in this study. Our study adds to the growing body of research that provides insights about how to ensure that the promises of informed consent will be fulfilled in a meaningful way for all communities regardless of cultural or ethnic make-up.

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Table 1

## Participant demographics

	Focus group								Total (n = 53)
	1 (n = 7)	2 (n = 6)	3 (n = 11)	4 (n = 8)	5 (n = 8)	6 (n = 5)	7 (n = 8)		
Response to question: "Do You Consider Yourself to be Hispanic or Latina/o?" (%)									
Yes	100	100	0	13	0	20	0	28	
No	0	0	100	88	100	80	100	72	
Responses to question: "Which Group Best Represents Your Hispanic Origin or Ancestry?" (%)									
Mexican	86	83	-	0	-	0	-	73	
Other	14	17	-	100	-	0	-	27	
Race (%)									
White	0	33	0	75	88	80	88	49	
White/African American	0	0	0	13	0	0	0	2	
White/Native American	0	0	0	13	0	0	0	2	
Asian	0	0	100	0	13	0	13	22	
Iranian	0	0	18	0	0	0	0	4	
Pacific Islander-other	43	0	0	0	0	0	0	6	
No response	57	67	0	0	0	20	0	17	
Age (%)									
18-24	14	17	0	25	0	40	0	11	
25-34	43	50	9	0	13	40	25	23	
35-44	0	33	73	25	50	0	50	38	
45 and over	14	0	9	50	38	20	13	21	
No response	29	0	9	0	0	0	13	8	
Monthly household income (%)									
Less than \$1,999-3,999	100	100	18	0	13	20	0	28	
4000-7,999	0	0	36	26	50	20	50	30	
8,000-11,999	0	0	36	38	26	40	0	22	
12,000 or more	0	0	9	38	13	20	38	18	
Educational level (%)									
Less than high school	14	17	0	0	0	0	0	4	
High school/GED	14	33	0	0	0	20	0	8	



Focus group	Focus group							Total (n = 53)
	1 (n = 7)	2 (n = 6)	3 (n = 11)	4 (n = 8)	5 (n = 8)	6 (n = 5)	7 (n = 8)	
College/vocational	14	17	18	38	38	40	0	23
Bachelor's degree	14	17	55	38	63	40	50	42
Higher degree	0	17	27	25	0	0	50	19
No response	43	0	0	0	0	0	0	6

**Table 2**

## Description of sampling areas

Group	Sampling area characteristics
1	Most populated city in county and fourth most densely populated city in US; 80% Latino; MHI \$43,412 (Group conducted in Spanish)
2	Second most populated city in county; 46% Latino; 24% Other Non-White; MHI \$47,122 (Group conducted in Spanish)
3	Smaller city; 59% White, 15% Asian; MHI \$55,985
4	Beachside city; 79% White; MHI \$81,112
5	Small planned community with gated neighborhoods; 78% White; MHI \$92,280
6	Master planned community; 82% White; MHI \$95,061
7	Planned city rated as one of the best places to live in the United States; 61% White, 30% Asian –American; MHI \$98,923

*MHI* median household income

**Table 3**

Themes: examples of cultural similarities and differences

Cross-cutting themes	Cultural differences			Cultural comparisons	
	White <sup>a</sup> (Groups 4, 5, 6, 7)	Latina <sup>a</sup> (Groups 1, 2)	Asian-American <sup>a</sup> (Group 3)	Similarities	Differences
Perceived risks	Participation increasing emotional impact of a pregnancy loss; risks to insurance coverage if a genetic risk is identified	Being judged by the researcher; detection for undocumented immigrants and possible consequences	Being “objectified”; conflicts between cultural values or practices and research participation	Receiving negative results; concerns about privacy and security; intrusiveness of visits; concerns about blood draws	Differences in identified emotional risks; differences in how study might conflict with values
Participant burden	Perceived need to get oneself and the house ready for a study visit	Number and length of the study visits	Long term commitment might “scare” people; perceived obligation to continue	Time commitment (number and length of visits); length of study	Degree to which the freedom to withdraw would address their concerns
Perceived benefits	Receiving results from environmental home assessments	Getting answers to questions about children’s health	Receiving information about the child’s development	Societal benefits; personal benefits; financial incentives	Amount of value placed on receiving child evaluations
Information needed to make a decision	Emphasize that the child will have a chance to choose to participate	Address the fears of undocumented residents	Describe prior similar studies and emphasize importance of study	Desire to have more information	Specific content and preferred methods for receiving information
What is the meaning of participation?	What will participation require (e.g., number/frequency of visits)?	Interpretation of participation in research as participation in a social service program	Desire to know how participation will help children across the country	Need to understand the meaning of participation	Interpretations of what research participation means; informational needs
Decision-making strategies	Decisions will be made by mothers and often fathers; other opinions will be considered	Families usually will decide together; opinions of others will be very influential	Families (including grandparents) will make decisions; opinions of elders will be influential	Use of risk-benefit analyses and social decision-making strategies	Who individuals will consult and degree to which other opinions will affect decision
Ease of participation	Socioeconomic advantage will make it easier to participate	Concerns that some will have about residency status will make it harder to participate	Short-term residency and degree of acculturation will impact willingness to participate	Belief that ease of participation will vary across communities	Reasons given for the perceived differences in ease of participation

<sup>a</sup>Described by predominant make-up of the group. There were within group differences in ethnicity (see Table 1)