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Strategies for Minority Recruitment in the National Children's Study: Issues of Trust

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EXECUTIVE SUMMARY

The National Children’s Study is a bold, ambitious, and innovative undertaking—a 21-year prospective cohort study to examine the relationships between a broad range of environmental, behavioral, biological, and genetic factors, and the health and well-being of 100,000 children across the United States. Opportunities to explore issues related to environmental and social justice as well as health disparities are inherent in this design. For these opportunities to be realized, the study seeks to recruit a nationally representative sample of childbearing women inclusive of minorities, especially African Americans, and retain participation of the children born to that cohort over the duration of the study. Issues of trust are critical.

The National Children’s Study has been planning for implementation of this study for the past 5 years. Multiple conferences have been held and white papers commissioned to provide recommendations to study planners regarding an expansive array of topics: scientific hypotheses and appropriate methodologies; sampling design and strategies; ethical challenges; community involvement approaches including a preliminary plan for field testing specific strategies in the North Carolina cohort; and recruitment and retention. Additionally, focus groups have been conducted with key community leaders and health care providers as well as prospective participants to identify issues related to study message development and factors facilitating and inhibiting potential participation. The findings from these collated works have provided the consortium of federal study sponsors with important information for study implementation. This consortium of federal agencies includes the United States Department of Health and Human Services, including the National Institute of Health’s National Institute of Child Health and Human Development (NICHD) and National Institute of Environmental Health Sciences (NIEHS); and the Centers of Disease Control and Prevention (CDC); and the United States Environmental Protection Agency (EPA).

Several of these white papers identified the influence of racism and discrimination on health and health outcomes as an important aspect of data collection over the course of the study. Concerns regarding issues of trust and fears regarding research participation among minority groups, especially African Americans, were mentioned as well. This white paper was commissioned to provide further details regarding the contextual influence of issues of trust and mistrust, influenced by racism and discrimination, as well as medical and research mistreatment of African Americans and other minorities, including women, on study participation. In response to the study planners' need to learn more about the potential impact of trust on study recruitment and retention, particularly of African Americans, the University of Mississippi Medical Center conducted a literature review and offered insights gained from the experience of Jackson Heart Study in recruiting approximately 5300 African American participants for study participation. This report summarizes that review and provides recommendations to the National Children's Study planners on recruitment and retention strategies that attend to issues of trust for African Americans.

The review and resultant strategies are based on a conceptual model that describes the various participant, organization, protocol, and community involvement (POPCI) factors and strategies that inform trust and research participation.

Our findings confirm that research participation for African Americans occurs within an overall social context of mistrust, fear, and apprehension. Trust—the expectation that something will occur as a given based on past occurrences—is built on a positive history of experiences at the interpersonal, institutional, and societal levels. Interpersonal trust arises from direct experiences with other individuals (e.g., researchers or health care providers), while institutional and societal trust are likely to incorporate a broader array of experiences. General impressions of institutions may be formed on the basis of personal experience as well as indirect experiences obtained through conversations with family or others, the media, as well as the sociopolitical or legal milieu regarding, for example, racial discrimination. Expectant trust is what the person brings to the situation—trust or mistrust uniquely discerned from these sources of information and experience. Experiential trust comes from repeated contact where positive experiences that convey caring, concern, competence, openness, and honesty breed trust; negative experiences weaken trust and often breed mistrust. Repeated positive interactions can make even the most skeptical gain trust; repeated negative interactions erode positive expectations or reinforce negative ones. Betrayal or breach of trust occurs when a trusted person or institution misuses trust. Once lost, trust is nearly impossible to recover. Where there are preexisting relationships, trust may be salvageable. For institutions, such breaches may be seen or feared to be systematic in nature. This type of breach has become painfully evident in the month post-Katrina where trust in the government and its agencies seems to have reached an all-time low.

As Vanessa Northington Gamble so eloquently proclaims, conducting research with African Americans occurs “under the shadow of Tuskegee.”[1] Trust in medical and research institutions was betrayed in this and other studies where African Americans were “used” to gain knowledge without benefit—in fact, with appalling detriment—for those studied. Such organizational mistrust has existed now for well over 30 years after the event. Despite misinformation about the study, its institutional effects have been far-reaching.

However, our findings suggest that Tuskegee cannot be imputed to be the single reason for African American under representation in medical research. Other historical legacies of oppression—the well-documented history of slavery, racism, and medical mistreatment—operate simultaneously. Some argue that racism no longer exists in the United States, and a recent review of available national survey data reveals increasing egalitarian attitudes among the white population.[2] Yet, these improving attitudes continue to coexist with a desire to maintain at least some social distance from blacks and a less than resounding commitment to social policies that aim to eradicate entrenched inequalities.[3] Likewise, endorsement of negative stereotypes of blacks among non-blacks persists. Considerable cultural support for racist attitudes, institutions, and policies is suggested by the persistence of negative stereotypes of African Americans. Analyses of the prevalence of lifetime, recent, and everyday racism experienced by blacks and whites in Detroit reconfirms that racism remains a significant obstacle for blacks, including the most successful.[4] Derrick Bell[5] in his book, *Faces at the Bottom of the Well: The Permanence of Racism,* contends that there is an illusion of equality because of the substantive gains African Americans have achieved over the past few decades. Through thought-provoking conversations with fictitious characters, Bell convincingly reveals hidden truths and places African American historical accomplishments in context. The theme of this book is that racism is an intrinsic, persistent, and indestructible element in our society. Like Tuskegee, it is a second shadow that follows African Americans wherever they go and impacts every decision they make.

Racial discrimination has had an implicit role in many societal policies including those on housing, education, banking, and real estate, as well as health care, among others.[6] These policies shape feelings of hopelessness and defeat and often prevent blacks from attempting to access services that might improve their circumstances. From the perspective of research participation, there may be socioeconomic differences in the way these legacies play out and the researcher’s perspective of race may influence available options for research participation.[7] For example, during recruitment and retention, women of color from low income strata may experience many instrumental barriers, such as inability to take time off work (multiple jobs), transportation, child care, linguistic proficiency, and so forth, while attitudinal barriers from institutional racism may influence the decisions of educated, higher income women of color. To date, little is known regarding these differences.

Detailed recommendations that emanate from our review of POPCI factors and strategies informing trust and research participation infer that the National Children's Study has a singular and unique opportunity to contribute to a better understanding of research participation among women and children of color across the nation. To what extent and by what methods is this study able to penetrate the "complex web of issues" where deep-seated and well-founded fears and apprehensions of research lie alongside optimism, hope, and a desire to contribute to the greater good, and obtain African American research participation? Thus, one notable summative recommendation is that the National Children's Study incorporates an embedded longitudinal study of research participation that:

- Selects communities with disparate demographic, geographic, and sociopolitical contexts in which to compare community-specific recruitment and retention processes and outcomes.
- Specifies a conceptual approach to recruitment and retention (e.g., social marketing, community-driven, participatory).
- Includes multimethod approaches to chart research attitudes and beliefs, measures of trust, impact of POPCI factors, and experiences and meaning of research participation or nonparticipation among those invited to participate and key community informants.
- Incorporates similar multimethod approaches to chart analogous factors among the research team and lead investigators responsible for recruitment and retention.
- Addresses ethical and cultural dimensions of research participation among all key partners.
- Details trust-building and damaging factors and strategies across the duration of the study.

I. INTRODUCTION

Purpose

The purpose of this white paper is to provide, under subcontract No. 192517 to Battelle, the National Children's Study Program Office at the National Institute of Child Health and Human Development (NICHD), a review of the literature and recommendations for strategies for minority recruitment that may be useful in developing methods for the National Children's Study. In particular, the focus of this literature review was to identify and characterize issues related to trust and mistrust, and associated fears and apprehensions regarding research participation among the African American community. The target population of interest was that included in the National Children's Study, specifically, women of childbearing age and their eventual children, though other populations were included as relevant to developing recruitment strategies.

Background

The National Children's Study, scheduled to begin recruitment in 2007, will be the largest and most comprehensive study of children's health and development ever undertaken in the United States. It will be conducted under the sponsorship of a consortium of federal agencies: the US Department of Health and Human Services, including the National Institute of Health's NICHD and National Institute of Environmental Health Sciences (NIEHS); and the Centers of Disease Control and Prevention (CDC), and the United States Environmental Protection Agency (EPA). It intends to enroll about 100,000 children, from before birth through age 21, by recruiting from among three distinct groups: pregnant women and their partners, couples planning pregnancy, and women of childbearing age but not planning a pregnancy. The National Children's Study will investigate connections between the environment and children's mental and physical development in an attempt to find risk factors and causes for many of today's major childhood diseases. Of importance, the study will try to identify harmful and harmless aspects of the environment, as well as genetic factors that may alter the effects of exposure, in both disease causation and healthy childhood development. The draft protocol for the study is demanding, requiring 15 in-person visits, some in participant homes and some in health care provider offices, over the duration of the observational protocol. Additionally, data collection via telephone, computer, or mail-in questionnaires will occur quarterly through age 5, and annually thereafter.

Biological samples from both mother and child, as well as environmental samples of water, soil, and dust will be collected over the years of the study.

The success of this ambitious undertaking will depend upon many factors, and key among them will be the study's ability to recruit and retain participants for the 21 years of follow-up detailed in the study design. The National Children's Study planners have systematically engaged a large number of experts and panels to explore many of the issues likely to impact study success. Issues include potential participant, community leader and stakeholder, and health care provider perspectives on study participation and design; ethical challenges; sampling designs; recruitment and retention strategies; and community involvement/engagement using community based participatory research (CBPR) initiatives. The influence of racism and discrimination on health and health outcomes was also considered as an important aspect of data collection over the course of the study.

With the commissioning of this review of the literature and white paper, the NICHD recognizes the potential importance of the contextual influence of issues of trust stemming from past and existing racism and discrimination, medical and research mistreatment of African Americans and other minorities, including women, in the US. The organization seeks additional information regarding how these issues might be addressed in the National Children's Study. The University of Mississippi Medical Center was identified to synthesize the relevant literature, provide insights gained from their experience in recruiting approximately 5,300 participants for the Jackson Heart Study, and provide recommendations for African American recruitment and retention in the National Children's Study. The University of Mississippi is the site of the Jackson Heart Study Examination Center. Carried out in the 3-county metropolitan statistical area surrounding Jackson Mississippi, the Jackson Heart Study is the largest longitudinal study of the risk factors and causes of heart disease in African Americans.[8, 9] While the reviewers recognized that other minority groups, particularly Native Americans, Hispanics, and Pacific Islanders, and more recently, Islamics, among others, experience ethnic and culture-based discrimination that may affect trust and research participation, these groups were not the explicit targets of this review. Reference is made to successful recruitment strategies for these groups within the document. The success of the National Children's Study will depend upon community-driven recruitment strategies that engage and incorporate the cultural exigencies of the population.

The Social Context of Trust

The Tuskegee Study of Untreated Syphilis in the Negro Male (Tuskegee) provides a metaphor for mistreatment and abuse of African Americans in the name of health research. The Tuskegee study was conducted by the United States Public Health Service beginning in 1932 and continued through 1972, until the news media exposed its policies to the nation. Its purpose was to examine the natural history of syphilis in 399 poor black sharecroppers from Macon County, Alabama, with latent (or noninfectious) syphilis and 201 syphilis-free controls. These men were recruited to participate in the study and monitored for 40 years using an unprecedented community-based strategy. This strategy employed an ethnically matched nurse and obtained cooperation of local black physicians within a historically black institution who served as the intermediary between the researchers and the study participants. While the study was never designed to provide treatment, these men were under the impression they were being treated for their "bad blood," receiving spinal taps and other procedures misrepresented to them as therapeutic. In exchange for their participation they were assured of free medical examinations and burial insurance, as well as some free meals.[10]

The study failed to educate or treat its participants, despite the development of adequate pharmacologic therapies for syphilis over the duration of the study. Not only the men who were study participants were affected. Though they were supposedly noninfectious, the *New York Times* reported in 1997 that by 1975, of 50 wives tested for syphilis, 27 were found to have the disease. Acknowledging the possibility that these women contracted syphilis from their husbands, the federal government agreed to provide lifetime medical benefits to 22 women, 17 children, and 2 grandchildren infected with the disease.[11]

Twenty-five years after Tuskegee was halted, President Clinton took a major step toward healing wounds and rebuilding trust by apologizing to the Tuskegee survivors, the nation, and African Americans in particular for this 40-year government study stating that "the legacy of the study at Tuskegee has reached far and deep, in ways that hurt our progress and divide our nation. We cannot be one America when a whole segment of our nation has no trust in America."[12] Vanessa Northington Gamble,[1, 13] the chair of the Tuskegee Syphilis Study Legacy Committee that called for the apology, chronicles in the report of the committee and her classic articles on the subject the multiple references in the professional and lay literature that attribute low levels of African American participation in clinical research as well prevention and treatment programs for cancer and HIV/AIDs,[14, 15] among others, on the mistrust created by the Tuskegee study.

Yet no consensus emerges from the research literature that Tuskegee actually has such a profound and singular impact on research participation (Table 1). These research findings have the potential to lull researchers into a sense of complacency potentially leading to ignorance of the larger societal patterns of abuse and mistreatment that are the more likely culprits. For example, as illustrated in a study by Freimuth and associates,[16] while most participants were aware of the Tuskegee study, many harbored misconceptions regarding the exact nature of the research abuses occurring in that study. An incorrect understanding of the actual details of the Tuskegee study is prevalent in the literature where this was assessed. These findings have great relevance for the National Children's Study, though it is also important to recognize that realistic constraints imposed by insufficient time, work, or family obligations, or by fears of needle sticks, can be readily interpreted by researchers as evidence of a minimal "Tuskegee effect." These actual reasons are indeed quite common and serve as realistic barriers to research participation among potential participants of all ethnic groups. For African Americans who live "betwixt and between" the black and white worlds, a sort of "double consciousness" ensues wherein trust in the truth and honesty of a received message can never be fully ensured. Dubois[17] first described this mode of situated decision making within an always changing panorama as follows:

> After the Egyptian and Indian, the Greek and Roman, the Teuton and Mongolian, the Negro is a sort of seventh son, born with a veil and gifted with a second sight in this American world—a world which yields him no true self-consciousness, but only lets him see himself through the revelation of the other world. It is a peculiar sensation, this double consciousness, this sense of always looking at one's soul by the tape of a world that looks on in amused contempt and pity. One ever feels his twoness—an American, a Negro; two souls, two thoughts, two unreconciled strivings, two warring ideals in one dark body, whose dogged strength alone keeps it from being torn asunder.

One of the ways of managing double consciousness is to tell others what they want to hear and thus avoid conflict. Operating within an overall context of fear and mistrust, instrumental barriers may provide an acceptable way to avoid explicating their deeper reasons for not taking part thus avoiding “being torn asunder.”

The literature does highlight a pervasive mistrust in research among African Americans including racial differences in the trust/information scores among parents.[18] White parents had significantly higher median scores, indicating increased levels of trust, compared to their African American counterparts. Hearing between the lines—listening for double messages and what cannot be said—will be important skills for National Children’s Study recruiters and investigators. But Tuskegee is perhaps not the only culprit in this legacy of mistrust.

Brandon, Isaac, and LaVeist[19] are among the most recent voices to call for an end of imputing Tuskegee as the sole reason for medical mistrust and lack of participation in medical research among African Americans. In this group’s most recent survey, they find that both blacks and whites shared the misperception that the men were actually infected with syphilis by the study team, and both ethnic groups believed that a similar study is still possible today despite all the safeguards put in place since that time. Blacks, regardless of their awareness of the study, were twice as likely as whites to believe Tuskegee men were intentionally infected and that it could happen again. Interestingly, race not knowledge of Tuskegee, was most predictive of mistrust in medical care. The researchers concluded that Tuskegee is not a primary reason for the medical distrust that is rampant among African Americans. Their findings are not surprising in light of the ongoing work that was initiated with the 1996 national study of research attitudes among 1,900 primarily white persons conducted by Kass et al.[20] regarding research attitudes. These investigators identified that trust in one’s physician was paramount. More recent evidence has continued to detail the inadequacy of the Tuskegee explanation in capturing the subtleties of African American fears and apprehensions regarding research participation.[16, 21-24]

Persistent racism—perceived or personally mediated, internalized, and institutional —also plays a major role in reduced trust and research participation. Personally mediated racism operates at the interpersonal level and is perceived in the subjective experience of prejudice or discrimination. This aspect of discrimination is what comes to mind for most persons when they hear the word “racism.” Overt and subtle experiences of unfair treatment are part of the fabric of daily life for most African Americans. Nearly one-half of non-Hispanic black respondents to a recent national survey reported experiencing at least one episode of major discrimination while more than 70% reported the occurrence of day-to-day perceived discrimination, either often, or sometimes. Nearly 90% reported race as the most common reason for discrimination.[25]

In societies with historical race discrimination such as the United States, negative self-evaluations of accepting negative cultural stereotypes as true (internalized racism) can have deleterious effects on African Americans willingness to even consider research participation. However, it is institutional racism that may have the most subtle influence on trust and the fears and apprehensions associated with research participation. As most research continues to be conducted by majority investigators, associated with majority institutions, aspects of institutional racism provide an important backdrop for under participation of African Americans in research. Jones[26] in her careful delineation of the impact of various levels of racism on health and health care decisions, defines institutional racism:

> … it is normative, sometimes legalized, and often manifests as inherited disadvantage. It is structural, having been codified in our institutions of custom, practice and law, so there need not be an identifiable perpetrator. Indeed, institutional racism is often evident as inaction in the face of need. Institutional racism manifests itself both in material conditions and in access to power…has its origins in discrete historical events but persists because of structural factors that perpetuate those historical injustices… [It] is because of institutional racism that there is an association between socioeconomic status and health in this country (p. 1212).

Institutional racism can lead to limited opportunities for socioeconomic mobility, differential access to goods and resources, and poor living conditions that adversely affect health, health beliefs, and trust in major social institutions. Beyond Tuskegee, other important examples of societal level discrimination include the 1967 Moynihan report, *The Negro Family: The Case for National Action*, which was commissioned by the Department of Labor and highlighted the “culture of poverty”—stating that African Americans were in poverty because they chose to be without regard for environmental or social conditions, and the 1996 *Bell Curve* report that used a “deficit model” to confirm racial characteristics as a basis for differences in intelligence. How researchers view and address these historical perspectives in research design and approaches to the African American community can influence the possibilities for improving research participation.

Despite inaccuracies regarding the specifics of the Tuskegee study, focus group and individual narratives with African American participants have consistently identified its legacy as an important factor that operates alongside other values and constraints against which the concerns and fears raised are weighed. Within a context of mistrust emanating from multiple sources beyond Tuskegee, many participants in this accumulated literature recognized the benefits of research and identified strategies that could increase their participation. For example, Freedman's[24] in-depth study of middle class African American women uncovered a "complex web of issues" where fears and wariness that are both deep-seated and well-founded coexist with feelings of optimism, hope, and a desire to contribute to health inquiry. Thus, taken together with earlier work, Brandon and colleagues' study[19] might more aptly be viewed as an illumination of the more widespread and deeply entrenched negative patterns of racism, and interactions with health care and other major systems that are the driving forces in medical research participation. Discerning how these pervasive patterns impact present day attempts to overcome longstanding disparities in research participation and health care for African Americans is far more nuanced than asking about respondents' knowledge of Tuskegee.

There is a growing body of literature illustrating the need to go further to consider other contextual factors and historical events that are important in shaping African Americans' general distrust of the "intent" of the white community and their fears and apprehensions concerning research participation. Among these concerns are the well-documented history of slavery, medical mistreatment, and racism, partially endured through cultural emphases on family and spiritual connection. Evidence of devaluing African American lives and humanity in the interest of research long predates Tuskegee, extending back to the time of slavery, when those enslaved were used for dissection, medical experimentation, heatstroke studies (for the purpose of extending their work hours in extreme temperatures), and surgical procedures without anesthesia.[27] Areas of distrust include widespread concerns about genocide (AIDS, Agent Orange, vaccinations, immunizations) and use of people of color as "guinea pigs" by the white establishment, particularly researchers.[11] A recent Institute of Medicine report[28] documented the extent of medical racism and the continued exploitation or mistreatment of minorities by medical professionals. Such evidence continues to confirm the fears and threats of African Americans toward research participation and health care. Chief among them are suspicion of researcher and health care provider motives—whether the best interests of the research participant or patient are the major consideration, and fear of exploitation or deliberate harm, particularly when biological specimens are involved. Participants in National Children's Study focus groups, especially those who were minorities or considered as vulnerable, expressed mistrust of research and the government, and that they wanted as much information as possible.[29] Similarly, a potential participant in the Jackson Heart Study[30] confirmed such concerns:

> I would like to know where this originated. If it was just a grant that was written, what institution, what institution wrote the grant? I want to know who the doctors are behind this. Are they black? Are they white? Do they really care? Or did they just write a grant to get some money out of the federal government? So, OK, we are going to study black folks now…for how long is the study going to go on? When this study is ended and the grant gone…are they just gonna [sic] submit their reports? Is it going to be continued? I want to know if this is all about money or is it about people? Right now I think we have a fear of its about money [sic]...we have been denied all these years and all of a sudden here's some money come and you are going to do a study on us. Is the study from the heart? Or they just gonna [sic] take the money and run?

For those who have experienced racism, a behavioral legacy is to be continually "on guard." The African Americans in the Jackson Heart Study Participant Recruitment and Retention Study[30] helped investigators understand that guardedness is "the way I live my life"—not because I don't trust you, but I have to find out." As one participant explained, "It is like I have to smoke you out…not that you automatically decide you can't trust [you], but before that trust is betrayed you just guard it. And it's automatic." Being on guard keeps a person safe. An interesting experimental study of methods of encoding messages under situations of trust and distrust provides evidence for this practice of safekeeping. Findings from 3 experiments suggested that, in situations of distrust, the cognitive system reacts by automatically inducing the consideration of incongruent associations—it seems designed to ask, "and what if the information was false?" This occurred even when the distrust had no meaningful relationship to the message and there was no way to prepare a strategic response.[31] A task for the research team is to learn to hear between the lines and listen for double messages—telling you what you want to hear to avoid conflicts, as well as instances of processing information for self-protection. For example, participants may ask some questions about the details of the study, but they may never say, or be able to say, that they have concerns. It is incumbent upon researchers to have an understanding of the practices of discernment—often learned and passed down through families—that help participants determine whether or not to trust. Listen as one Jackson Heart Study potential participant summarizes these practices:

> I appreciate the fact that I have that [being on guard] and what it does is enables my discernment of the person that I am dealing with…Well, you know, you learn to read people from insight. So it's not just reading what's on the surface because I see you smiling and I see you putting out your hand to shake my hand and I hear the words, "Hi. How are you today?" Well, see I learn to read you and it's like I can read between the lines. I see the real person. It doesn't matter what I see, it's what I feel. And you know when to pull it back a little bit. Sometimes you figure out maybe I shouldn't come to this conclusion because I am taking this thing [guardedness] too far. Maybe like giving the benefit of the doubt. There's always doubt. It's hard. I mean, it's complicated…But it's not a personal thing toward you. And it may come across as being rude or what have you, and you may take it personally. But generally that's not the case. The person is being standoffish until they get a feeling of the real person they can trust.[30]

Decision making for research participation is likely to be communal and consulting with family is commonplace. As the women in Freedman's[24] study articulated:

> We have been raised—and I am talking about the generic "we"—to be mistrusting, and only to trust the family. You go to the family for strength and that is probably why black folks survived, because of the family strength.

Family is central in the African American community. As DuBois[17] noted in the early 1900's, commitment to the family is the most fundamental value in the African American community. A strong sense of obligation to "blood" relatives as well as kindred groups that transcend individual households are features of family life sustained from African heritage. This transcendent or extended family often includes non-kin. African-Americans are descendants of a culture organized around the socio-spiritual ethos of "persons in relation"—the deepest elements of that culture derive from a communal essence.[32, 33] The tradition of "helping out" goes beyond blood relationships to community and consists of providing services, goods, and money as well as intangibles such as emotional support in coping with harsh and oppressive environmental conditions. This concern for other persons, not restricted to blood kin, has been dubbed by scholars as "fictive kin" with the creation of "social families." Black churches are often the "structural locus" for these social families or, as one participant told us "the seat of the Black community." Persons meet here and forge the bonds of family. Families, whether blood or social, are primary groups. Cooley[34] identifies a primary group as "a 'we' which involves the sort of mutual identification for which 'we' is the natural expression" (p.23). This powerful sense of "we-ness" supplies members with identity, meaning, security, and belonging.

The religious community emphasizes and extends the nature of family and provides a source of relationship networks, solidarity, and trust. Particularly in the South, religion and spirituality offer an important social resource that may contribute to understanding black health status over the life course.[35] The black church has served as the institutional and symbolic center of African American life, offering both an "otherworldly" focus in the midst of adversity as well as a place for the development of black leadership, politics, and mutual aid. African American religious views have been characterized as "escapist" with rewards to be obtained at some later time in the spiritual realm—"I will leave it in God's (Allah's) hands." However, this view gives insufficient attention to the activist functions of religion in this group. It is quite possible that fatalistic orientations coupled with high levels of religious involvement are particularly adaptive for African Americans and play an important role in decisions regarding research participation.[36]

Preliminary work for the National Children's Study identified issues of trust as "the most important barriers to participation."[29] Trust is predicated on experiences from the past. Interpersonal trust arises from direct experiences with other individuals (e.g., researchers or health care providers) while institutional and societal trust are likely to incorporate a broader array of experiences. General impressions of institutions may be formed on the basis of personal experience as well as indirect experiences obtained through historical references (e.g. Tuskegee); from conversations with family or others; media portrayals; the sociopolitical or legal milieu regarding, for example, racial discrimination; as well as the culturally developed practices of safekeeping (family and spiritual connections).[7, 37] Several types of trust impact decision making regarding research participation. Expectant trust is what the person brings to the situation—trust or mistrust. Experiential trust comes from repeated contact where positive experiences that convey caring, concern, competence, openness, and honesty breed trust; negative experiences weaken trust and often breed mistrust. Repeated positive interactions can make even the most skeptical gain trust; repeated negative interactions erode positive expectations or reinforce negative ones. Betrayal or breach of trust occurs when a trusted person or institution misuses trust. Once lost, trust is nearly impossible to recover. Where there are pre-existing relationships, trust may be salvageable. For institutions, there are fears that such breaches are systematic in nature.

Gilson[38] in her seminal evaluation of the contribution of trust to the development of health care as a social institution provides a synthesis of theoretical perspectives on the notion of trust that are relevant to research participation. Using this synthesis as a basis, she argues that "trust underpins the cooperation within health systems that is necessary to health production" (p1454). Similarly, trust underpins the cooperation within the research enterprise (and within particular studies as exemplars). Trust is necessary to generate knowledge for health benefit. According to Gilson's theoretical synthesis, trust, in its most basic iteration, is a relationship that lies between people, between people and organizations, and between people and events. Interpersonal trust occurs between persons known to each other. Impersonal trust occurs between strangers and in social systems. Both forms are based in calculative or affective bases—a cognitive calculation that the actions of the other party will produce more benefit than harm, thus outweighing the inherent risk or an act of faith expressing commitment to something beyond cognition. Cognitive-based trust may evolve toward altruistic-based trust. Even when initial trust occurs through a rational gamble that other's best interests are served by cooperating with you, experiences and interactions over time can produce knowledge-based expectations of trusting behavior, ultimately generating identification-based emotional ties, shared values, and altruistic trust.

Researchers engage potential participants as "strangers in our midst" who must supply adequate information for participants to use in judging the warrant of the request. That may come in the form of known persons vouching for the "stranger's" reputation, from shared group norms, or from institutional affiliation with agencies whose social norms are sufficiently persuasive and have recognized moral value backed up by powers of enforcement when norms are ignored to motivate involvement. To be successful, each research study must devise specific strategies of recruitment and retention that attend to these elements of building trust.

Participants in National Children's Study focus groups specified barriers to trust that included study legitimacy, sample use and handling, confidentiality, and general mistrust relating to issues of institutional racism. For research participation to occur, study information and interactions have to address these barriers in a manner that engages the individual's past experience and proactively demonstrates legitimacy and trustworthiness of the study organization. We reviewed the literature on ethnic match, compatibility, and continuity of study personnel contacting participants (presented below), as some factors to consider in this regard. A great deal of skill and sensitivity is required to facilitate meaningful engagement of past experiences. Studies such as the Jackson Heart Study have put in place staff selection practices that emphasize interpersonal abilities and commitment to the study purpose, including community involvement in hiring.[39] Recruiters were provided with a variety of informational tools from a wide range of organizations and groups from which they could select. For example, the recruitment packet included letters of support from mayors, the NAACP, the ministerial alliance or representative ministers, as well as from key community spokespersons. As well, it is crucial that research organizations confront their organizational culture, addressing issues of reputation in the community.

While the lead author of this report is not African American or Latino, and thus can never fully understand all of the racial issues involved in minority recruitment, extensive experience from the Jackson Heart Study and other minority research and clinical endeavors has underscored that in order to be successful in recruiting, researchers of whatever ethnicity must be willing to confront issues that reveal the inherent racism in this country, and include this understanding in developing community driven recruitment strategies. Consideration of other contextual factors that reflect African American (or other minority) culture such as family and spiritual tradition, concomitant recognition of the heterogeneity of any ethnic group, along with extensive self-reflection and action regarding research organizational values and perspectives is essential.

Assumptions and Definitions

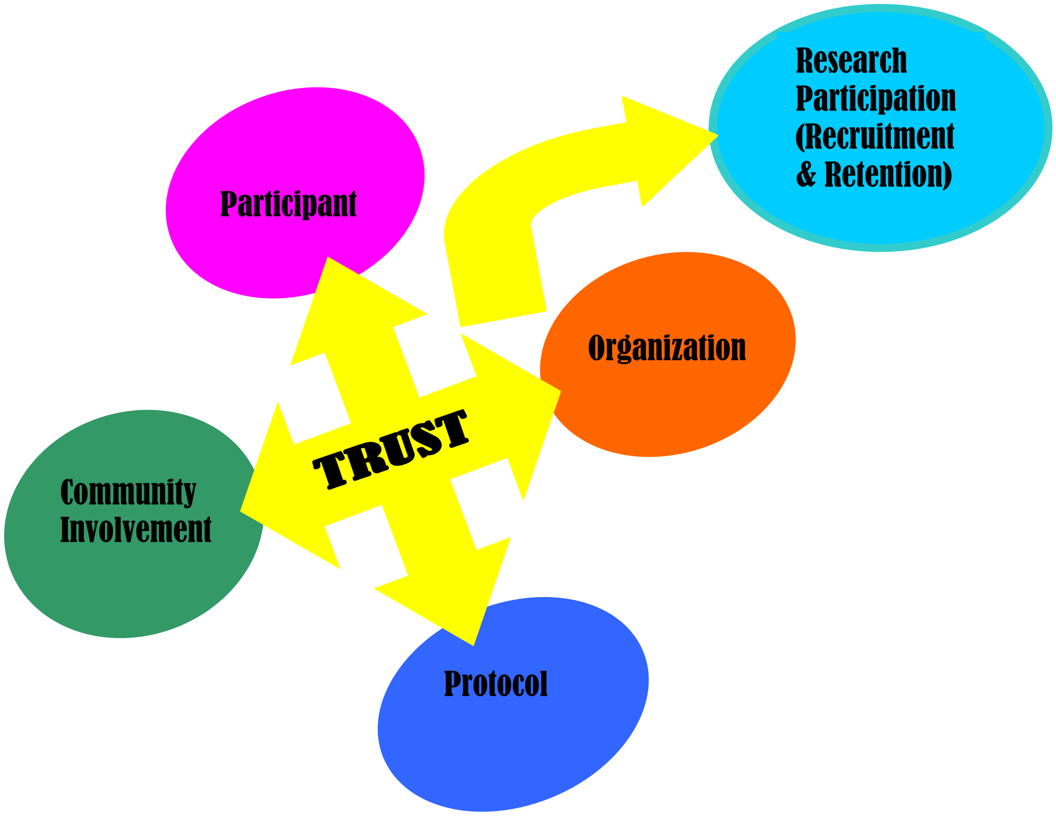
Although it is important to understand that women of color are quite heterogeneous, as are all similarly defined groups, certain historical experiences are common and account for certain attitudes and perceptions. Thus, an underlying assumption of this review of literature is that there is a shared heritage of racism and discrimination coupled with unique individual experiences that underlie African American women's consideration of research participation for themselves and their children. Crucial to this experience is an operational definition of trust. The definition presumed for this review is "trust is the expectation that something will occur as given by the past"[30] and may function at the interpersonal, institutional, or societal level.

Conceptual Framework (POPCI Model of Recruitment and Retention)

The conceptual framework guiding this project addresses the interaction of trust and key barriers and enablers of research participation in African Americans. Wyatt et al.[30] synthesized this model prior to conducting a study of factors likely to influence research participation among African American adults in the Jackson Heart Study. Three data sources were used in developing this model: reading across the extant literature on recruitment, interpretation of dialogue with researchers and staff of other minority studies, and interpretation of interviews with staff in the Jackson, Mississippi, site of the Atherosclerosis Risk in Communities (ARIC) study (the precursor to the Jackson Heart Study). An extensive review of the literature on recruiting and retaining research participants in a variety of scientific studies, notably clinical research, clinical trials, as well as longitudinal cohort studies such as the Jackson Heart Study (and the National Children's Study) was conducted for the years 1985-1999. As little specific information was available in the extant literature regarding the realities of recruiting and retaining African Americans to research participation, the literature was supplemented with in-depth interviews with researchers in African American studies who were directly involved in the process of recruiting. Additionally, we interviewed the ARIC staff members who were responsible for initial recruiting, for ongoing retention, and for enacting the protocol for data collection. These three pivotal information sources provided the background for developing an innovative conceptual model of factors thought to simultaneously and interactively influence research participation, recruitment, and retention by influencing trust.

As seen in Figure 1, the model incorporates the key elements of Participant, Organization, Protocol and Community Involvement (POPCI) as they link with the central element of trust and the expected outcome of research recruitment and retention. The center multidirectional arrow reflects that all elements turn on issues of trust and mutually influence each other to effect research participation. Each construct comprises both barriers and facilitators of research participation designating factors influencing participation and strategies that researchers might employ to achieve research participation. Factors are generally mentioned as influencing the success or failure of recruiting participation or as impacting trust. Strategies are actions used to enhance trust, overcome barriers, and improve research participation—either actually taken, or lessons learned. No construct stands alone; each is in constant interaction with every other element, modulating trust, to predict research participation.

Figure 1. Participant, Organization, Protocol, Community Involvement (POPCI) Model of Research Participation (Recruitment and Retention)



Participant Influences. Participant influences are those factors or strategies related to individual participants. Four participant influences were identified.

- <u>Personal demographics and networks</u> include factors such as age, gender, ethnicity, occupation, income, marital status, geographic and neighborhood location, personal resources including access to transportation and health insurance, religion, social resources including networks of family and friends, family and other time commitments.
- <u>Health status and risk factors</u> include overall health rating, disease burden, health behaviors or exposures such as smoking, alcohol consumption, diet, physical activity, unsafe neighborhoods (crime).
- <u>Health beliefs, attitudes, and experiences</u> include elements of personal control, mastery, fatalism, explanatory models of disease, health care access and use, personal (or significant other) experiences with health care and health care providers that influence trust in health care received.
- <u>Research beliefs, attitudes, and experiences</u> include factors of personal benefit, community benefit, ethnic benefit, altruism, ethics, knowledge or personal experience with research, including stories of Tuskegee or other research abuses passed down through the generations that influence personal research attitudes and beliefs.

Organizational Influences. Organizational influences are those factors or strategies related to basic elements of organizational structure, function, hierarchy, and climate of the research institution, extending beyond these to include additional aspects of continuity, commitment, and compatibility. Specifically, 4 elements are included.

- <u>Compatibility of participants, staff, and researchers</u> includes cultural sensitivity and ethnic and gender match between researchers and participants, as well as researcher and staff attitudes, values, and motivation regarding research in general and the particular initiative. These latter factors are included in this category as researchers and staffs never operate in isolation; they are inherently part of the larger research organization.
- <u>Organizational climate, governance, and institutional factors</u> addresses such issues as staff morale and satisfaction, the overall climate or “feel” of the work setting, the type of governance, degree of bureaucracy or flexibility to meet study objectives within the governing organization, organizational commitment to the study, as well

as resources available for carrying out the work, the training of staff and researchers, and the leadership both within the organization and the study.

- Continuity includes the ongoing contact and communication among researchers, staffs, and participants—their level of bonding, the stability of the study staff such as staff ownership and involvement in study design and operations, and the mutual agreement of all to pursue study goals.
- Accessibility and aesthetics identify the factors regarding the study site and location, its accessibility to the majority of participants, ease of parking, as well as the overall environment of the site—its physical attractiveness, comfort, cleanliness, and friendliness including availability of literature, videos, a minimum of waiting time, and conveyance of a sense of caring.

Protocol Influences. Protocol influences are defined by the factors or strategies related to carrying out the research plan. Four influences were identified.

- Research design factors include the requirements of the sampling plan, eligibility criteria, recruitment and retention methods, data collection and instrumentation, and data management systems.
- Consent incorporates the ethical issues relevant to the conduct of the study as well as the details regarding participant expectations, burden, confidentiality and other means of protection, personal benefit, and incentives, as well as readability of the forms.
- Accommodation to the participant addresses specific strategies employed as part of the protocol to improve the research experience and make it possible for participants to complete the protocol. For example, contact frequency, tailoring the protocol to individual participant needs, flexibility in scheduling and other parameters, reminders and follow-up, as well as creativity in overcoming barriers are included in this factor.
- Quality assurance and control is the final aspect of protocol influence with rapid feedback on study results to participants and study performance to staff, as well as tracking systems to maintain oversight of all elements of protocol implementation.

Community Involvement Influences. Community involvement influences include the factors and strategies related to societal and community perspectives of research participation. While these factors may influence individual or personal factors, the emphasis is placed on the broader social context.

- Mobilization encompasses awareness and knowledge of research in general and of a particular research project within the community of interest. Generally, mobilization is a limited type of involvement aimed toward "getting the community ready" for an upcoming project already designed by outside persons. Social marketing and other similar strategies are employed.
- Partnership is the next level of involvement and entails ongoing participation and leadership of the designated community in all phases of the research endeavor. This element addresses issues of control and power sharing, and ongoing community empowerment in defining research questions and designing culturally appropriate approaches to answering them.
- Translation is the reciprocal "giving back" to the community, including disseminating study findings in a wide variety of venues such as newsletters, seminars, community speaker groups, and other forms of education.
- Social context and related concerns/issues designates the cultural milieu that surrounds research participation in general, and the unique aspects of the community under study—social, cultural, political, and economic as well as the lifestyle, needs, and desires of the designated community.

II. METHODS

The literature search was accomplished by 1) consulting previous National Children's Study reports and documents in the areas of recruitment, retention, and communications, and 2) enhancing the original literature search on recruitment and retention conducted for the Jackson Heart Study Participant Recruitment Study.

Identifying Relevant Literature

Existing National Children's Study Documents

Documents reviewed included:

- Growing Up Healthy
- Communications Strategy for the National Children's Study
- EPA Focus Groups
- Ogilvy PR Focus Group Reports
- Minutes and Reports of the Community Outreach and Communications Working Group
- Minutes and Reports of the Health Disparities and Environmental Justice Working Group
- Report from the Workshop "Measuring Racial / Ethnic Discrimination and Racism from a Developmental Perspective" held in 2004
- Other related documents

The review of this material was conducted to provide background and context for the current review and was not included in tabular summaries.

Updating Previously Conducted Literature Review

This review of the literature is built on the foundation established with a previous review conducted for the Jackson Heart Study regarding the recruitment and retention of African Americans in research studies. A relatively comprehensive compilation of relevant literature was compiled during that original review for the years 1985-1999. This original search has been updated periodically and new citations added. All citations are maintained in the Jackson Heart Study EndNotes® bibliographic database which includes a wide array of citations relevant to the study objectives. The original Jackson Heart Study recruitment search strategy was conducted using several online bibliographic data bases including MEDLINE, CINAHL, PubMed, Sociological Abstracts, HealthStar, PAIS, PsycInfo, Dissertation Abs Online, and Social Science Abstracts. Using the POPCI model as a framework, all identified citations relevant to recruitment were coded in the Jackson Heart Study bibliographic data base with any of the following key words: recruitment, retention, research participation, African American, Latino, Hispanic, Native American, minorities, women, men, adults, longitudinal study, population study, cohort study, clinical trial, participant, organization, protocol, community involvement, trust, Tuskegee. Those citations that were not coded included one or more of these key words in the title.

The first step in conducting the National Children's Study literature review was to conduct a key word and title search of the Jackson Heart Study bibliographic data base to extract all relevant citations into a separate EndNotes® library. A total of 355 citations were transferred to the National Children's Study recruitment EndNotes® library created for this project. A hard copy of each citation is maintained in an individually labeled file folder. All hard copies were pulled from the Jackson Heart Study filing system and transferred to the National Children's Study project files. Next, a new literature search was conducted for the years 2000-2005. Due to time constraints, a less extensive selection of electronic bibliographic data bases was employed than was used in the original Jackson Heart Study search. This updated search included MEDLINE, CINAHL, PubMed, and PsycInfo. This bibliographic search did include mainstream scientific and medical journals, including those focusing on women's and pediatric health. As the initial literature review focused primarily on adults, the updated review included a focus on women, children, and adolescent females who are members of diverse cultures. Combinations of the keywords indicated in the table below were used, and additional citations were identified through search of the bibliographies of reviewed articles. This search yielded an additional 135 citations. Hard copies of all citations were obtained and added to the individually labeled project filing system.

Bibliographic Search Keywords and Synonyms	
Keywords	**Synonyms**
Recruitment	Research participation Retention
African American	Minority

	Ethnic
Trust	Tuskegee Mistrust Fears
Community	Community involvement Participatory research
Women	Females
Adolescent	Teenager
Research	Cohort study Clinical trial Longitudinal study

Selecting and Categorizing Relevant Literature for In-depth Review

Using this combined search strategy, just over 500 citations were located. The full list of titles was reviewed for direct relevance to the National Children's Study and the target of this literature review: strategies of minority recruitment and issues of trust. Employing the POPCI model to guide the process, criteria used for selecting potential citations for in-depth review were:

1) Does it offer information beyond that already addressed in prior National Children's Study commissioned recruitment materials?
2) What is the contextual influence of trust, mistrust, fears, and apprehensions on African American research participation?
3) What is the ongoing effect of the Tuskegee Study of Untreated Syphilis on African American research participation?
4) What are the key factors influencing trust and participation?
5) What are the recruitment and retention strategies for overcoming mistrust and enhancing research participation in African Americans?

Additional criteria used for priority selection of literature for review included whether the study focused on children or women of childbearing age, relevant health outcomes, and length of the study. Citations that focused on men and the elderly were included for review in instances where they could contribute to understanding the contextual influences of the family on trust issues in research participation. Likewise clinical trials and prevention studies were included where they could contribute to understanding relevant factors and strategies.

Titles of all citations were reviewed to eliminate any that were obviously unrelated to the task at hand. This cursory review eliminated approximately 300 citations from in-depth review, however all citations were retained and annotated to generate a bibliography to provide additional information to the National Children's Study regarding the extent of potentially relevant literature. The remaining approximately 200 citations were retrieved and sorted by POPCI category, assigned a priority level for review, and then distributed to the review team. Priority 1 citations were those deemed most immediately relevant to the National Children's Study while Priority 2 citations were those that had apparent relevance, but not as directly applicable as those designated in the first category. Due to the constraints of time, a fully exhaustive review of all available literature was not completed. All Priority 1 and Priority 2 citations were reviewed and coded, but not necessarily included in the summary tables.

Coding Strategy

All reviewed citations underwent in-depth review identifying content specific to the POPCI model. The lead author coded all citations categorized as related to trust or mistrust, those that were directly related to the National Children's Study population, and at least 25% of those designated for review in each of the categories of participant, organization, protocol, or community involvement. These citations were coded across all POPCI categories. All other reviewers coded citations in one designated category. This strategy was adopted as the most efficient review process to assure wide coverage of the literature given the short time span available.

The lead author had extensive experience using the model as a framework for coding and was well-versed in the recruitment literature. The remaining members of the team had extensive experience in conducting literature reviews in their areas of expertise, but had little familiarity with the research recruitment literature. Two intensive training sessions of several hours duration were conducted with the entire team followed by individual sessions as needed. A coding strategies form (Appendix 1) was developed to provide detailed instructions for each category and subcategory of the model. Definitions and criteria for each component of the model were discussed. The process of coding using colored highlighting to designate the specific category of the model and a written alphanumeric code corresponding to the subcategory (e.g. Participant=pink highlight with P1F or S to designate a demographic/social network factor or strategy, etc.) was reviewed. Instructions regarding overall and detailed summary comments were provided in the first session. Each reviewer independently coded 2 articles for all categories, and a second session was conducted to discuss coding outcomes in comparison with each other and the lead author. Discrepancies were clarified and 2 additional articles were coded in the same manner with individual follow-up with each reviewer until each reviewer and the lead author had an acceptable inter-rater reliability (>80%).

As citations were distributed, each reviewer received summary coding and comments forms with the citations already entered. All completed codes and summative comments were transferred to this form and combined with the coding of other reviewers to develop final coding results tables. Summary tables for each construct were then created using the coding tables as a guide (Appendix 2).

III. RESULTS

Tables 3-5 (Appendix 2) provide a tabular summary of the key results and comments from the priority literature reviewed. Tables are organized according to the 4 recruitment factors and strategies: Participant (Table 3), Organization (Table 4), Protocol (Table 5) and Community Involvement (Table 6). This section provides a narrative summary of the major findings and potential recommendations for the National Children's Study in each area of the POPCI model.

Participant Factors and Strategies Influencing Trust and Participation

Table 3 summarizes the participant factors and strategies influencing trust and research participation. The literature identifies a number of important issues related to personal, logistical, and financial needs; social networks, including family, friends, and health care providers; health care and research experiences, attitudes, and beliefs.

Findings

Personal Demographics and Networks. Personal demographic characteristics such as age,[27, 40-46] gender,[41, 42, 44-50] race or ethnicity,[40, 42, 44, 45, 50-54] educational status,[21, 27, 42, 48, 53-55] marital status,[46, 53, 56] employment,[48, 52, 53, 57] socioeconomic status,[27, 41, 43, 46, 47, 50, 53, 57-59] and geographic area[27, 56, 60] have all been identified as factors impacting trust and research participation. Women and younger persons are generally more likely than men and elders to participate, as are persons who are married, employed, and have higher levels of education and income.

Killien and others[61] examined factors associated with participation in clinical trials at the National Centers of Excellence in Women's Health. Common barriers to participation were classified as availability, accessibility, and acceptability. These barriers occurred because studies were conducted in places or at times that were incompatible with potential participants' schedules or living arrangements. Transportation to the research center was difficult for women who must use public transportation, depend on spouses, or dislike driving in inclement weather. Scheduling time to participate in research activities may be difficult for women with responsibilities for the care of children or other family members, and those who may have difficulty scheduling time off. Furthermore, safety concerns, poor literacy skills, and language concerns impaired potential participants' willingness or ability to participate.[51, 53, 58, 61, 62]

Three groups of researchers investigated factors influencing the recruitment and retention of infants and children into research studies. Harth and colleagues[63, 64] compared sociodemographic characteristics, attitudes, and psychological profiles of 68 Australian parents who allowed participation with 42 parents who refused participation of their children in a clinical drug trial. Compared to those who refused to participate, participating parents had less education, were less likely to work in professional and managerial jobs, and had fewer close friends and confidants.

Investigators in the Bogalusa Newborn-Infant Cohort Study followed a cohort of 440 infants from birth to 7 years of age.[65] There was a gradual decline in participation as the age of the child increased. Compared to white children, African American children had higher refusal rates but, once enrolled, a higher percentage of African American children were retained over the 7 years of the study. Reviewing the entirety of participation in the Bogalusa Heart Study (1973-1982), researchers identified that ages 13-14 were crucial for decision making regarding continuation. Participation was higher among those with high scholastic achievement as well as other key attitudinal and behavioral factors. No specific medical or physical differences were noted between participants and nonparticipants. Parental refusal was the most common reason for nonparticipation.[66]

Some investigators found recruitment and retention was particularly difficult in predominantly African American communities,[40, 58, 67] while others found no racial differences in the rate of participation.[68] For example, Advani and associates[40] examined the willingness to participate in research in 420 oncology patients. As with other studies, these investigators found willingness to participate was associated with younger age, higher income, and higher educational level. On the other hand, in their study of the efficiency of various recruitment strategies for the enrollment and retention of minority women into a community based longitudinal study, Gillis et al.[68] noted similar rates of recruitment among African American (46%), European American (51%), and Hispanic American women (44%). Similarly, in 4 hypothetical chemoprevention trials, Blumenthal and associates[56] reported no ethnoracial differences in the intention to participate among 238 underserved women attending colposcopy clinics.

Poverty and lower socioeconomic status (SES) have been identified by several investigators as major obstacles to participation by African Americans and other racial minority groups.[50, 54] Race often serves as an unfortunate proxy for poverty and is thought to exacerbate barriers associated with child care, transportation, and financial restraints associated with the hidden costs of research participation.[58, 69] Scheduling of both work and personal time are common instrumental barriers to participation. Research that provided resources to overcome these barriers reported more successful recruitment.[43, 70] Race and poverty also limit access to primary health care and thus to physicians and other health care providers who may notify participants about research projects and encourage participation.[42, 50, 62, 71] Less access to care can also facilitate enrollment. Some participants have identified the opportunity to receive state-of-the-art health care as an incentive for research participation.[55, 56]

Women are often the gatekeepers to the family and serve to negotiate major decisions, such as research participation within their family structure and community networks. For example, despite the sensitivity of the study focus, the majority of eligible women in a HIV/STI prevention trial were able to recruit their male partners into the study.[70] In ethnic minority communities, elders within the community, the family, or other entities such as the church, often provide an immutable resource to individuals and families as they make decisions regarding important life issues, including research participation.[24, 40, 44, 48, 52, 58, 72-80] Thus while individual characteristics of the target community are important factors, so are the networks with which potential participants interact. These networks may exert social pressure toward or away from participation by providing or withholding adequate social support. Levkoff and Sanchez[44] related an incident in which a Chinese American participant would not agree to participate until she talked with an uncle who was considered the elder in her family. Similar examples were common in the Jackson Heart Study, particularly as participants considered taking part in the family (genetic) study component. Though wives, mothers, or grandmothers often served a pivotal role in family decisions regarding research participation, they did so in consultation with important family members, including elders.

The role of elders and others in women's social networks is a major source of ongoing influence. These interactions link current decision making of younger generations of African American women with past egregious research and other relevant experiences, attitudes, and beliefs: though they may have no first-hand knowledge of these events or practices, younger women are influenced by those who do. Researchers must be aware of these influences, providing ample time for discussion with potential participants and, if necessary, their families or significant others. Banks-Wallace, Enyart, and Johnson[81] found preintervention meetings with a nurse practitioner was an effective recruitment strategy for 25 African American women participating in a physical activity intervention study. During the preintervention meetings, women were able to discuss their concerns regarding the research, and researchers were able to highlight the benefits and address barriers to participation. Similar prestudy enrollment "family meetings" facilitated by recruiters might provide important opportunities for discussing issues central to participation. As well, a Council of Elders—a group of ongoing research participants from the ARIC study—was organized in the Jackson Heart Study to provide a "supportive presence" and source of primary information about research participation for the community.[30, 82] Given the reliance on social networks for decision making among female African Americans, adverse beliefs among elders and other family members pose a potential obstacle to effective recruiting for the National Children's Study.

In long-term studies such as the National Children's Study, retention is also a concern. Many of the same factors influencing recruitment also influence retention.[41, 46, 51, 55, 56] Davis and her associates[83] reviewed the literature and found participants who were older, nonwhite, had limited education, multiple health problems, increased life stress, and a pattern of erratic health care use were more likely to drop out of research studies as compared to their counterparts who did not have these characteristics. Likewise, Ahluwalia and associates[55] found African American smokers who were male and those who had less than a high school education were more likely to drop out of a smoking cessation trial. However, younger smokers were more likely than elderly smokers to drop out.

<u>Health status and risk factors.</u> The health status and personal health practices of participants influenced the willingness to participant in research studies. Poor health has been associated with reduced research participation, especially in older adults.[42, 56, 71, 72, 79, 80, 84] Little is published about health status factors of adolescents or women in longitudinal

studies. The Right From the Start study did find that African American women participants were more likely to have concerns about their pregnancy and typically reported less favorable health behaviors.[54] The issue seems to be one of relevance as well as personal health benefit.

Lifestyle factors such as smoking and alcohol use have been associated with willingness to participate in research. Harth, Johnstone, and Thong[64] found a higher percentage of participating parents consumed alcohol or caffeine and had someone in their families with serious illness compared to parents who refused participation. Interestingly, other researchers have found smokers are more likely to drop out or not enroll.[46, 55] Conversely, persons in excellent health may also be difficult to recruit, particularly to observational studies, because they do not perceive a benefit for themselves.[24, 85] However, recent literature on recruiting to preconception studies assessing reproductive and developmental toxicants indicates that it is certainly possible to recruit sufficient women and children for longitudinal study.[86, 87]

Health beliefs, attitudes, and experiences. Health status and risk factors interact with issues such as personal empowerment around illness, access to health care, insurance, and quality of service. Attitudes and beliefs about health, including religious beliefs, can serve as important facilitators or deterrents to research participation.[48] Knowledge and the perception of the importance and pervasiveness of a particular health issue or disease in an ethnic group can impact research decision making. For example, the stigma associated with mental illness can be a deterrent to research participation.[41] When the disease is highly prevalent in the population of interest, for example heart disease among African Americans, potential participants often perceive this as an incentive to enrollment—the opportunity to learn more about the specific condition for themselves, their families, and their community. For some, however, the fear of obtaining negative health information can foreclose on research participation. Explanatory models of disease causation may also serve as barriers or facilitators of research participation.[88]

The literature identified fatalistic health attitudes as another contribution to nonparticipation. If an individual believes that the onset of disease is a punishment from God because of a lifestyle choice or decision, the person is less likely to participate in health prevention activities such as research, because they do not believe it will do any good. Advani and associates[40] found a belief that God would determine whether or not they were cured was a significant deterrent to willingness to participate in clinical trials. The researchers thought this belief contributed to racial differences in willingness to participate because a higher percentage of African Americans held this view. In addition, if religious beliefs prohibit or proscribe research participation, then persons who ascribe to these traditions may opt not to be part of any "experimentation" on the human body.[50] Knowing the target population beyond its statistical information is important to developing strategies that value and respect its belief systems.

The support of trustworthy providers has provided an important strategy for effective recruitment in multiple studies, including those with African Americans.[48, 72] Gorelick and colleagues[86] suggested that the support of a "recruitment triangle" composed of the participant, key family and social networks, and medical personnel is necessary for successful recruitment of African Americans. Alternatively, some research participants have expressed mistrust of their physicians[22, 89] and the health care system,[57, 81] which may influence their willingness to participate in research. Advani and associates[40] found advice of physicians and the potential benefit to others had less influence on the decision to participate among African Americans compared to whites. Furthermore, elderly participants in a study conducted by Moreno-John and associates[57] believed their physicians would expose them to unnecessary risks if they participated in clinical research. The support and study knowledge of health care providers was an important component of research participation for some participants in the Jackson Heart Study. Beginning prior to the study start, information sessions were hosted with community providers to update them on study goals and progress. Information fliers and study newsletters were distributed to their offices and a Jackson Heart Study network of providers was identified to accept referrals for persons without insurance or established providers. Having these strategies in place provided a useful resource when recruiters were faced with the response that "I already have a doctor." Awareness that participation was supported by area health care providers and that participation did not circumvent or alter their primary health care provider relationship facilitated participation for some individuals.

The lack of health insurance has been associated with decreased participation in research,[42, 48, 50, 90, 91] largely from diminished access to providers who can notify potential participants about research studies.[49, 51] In focus group interviews with 33 African American adults, Corbie-Smith and others[75] found younger participants were motivated to participate in research studies because of the possibility of receiving access to state-of-the-art health care, medications, and alternatives to standard treatment. Harth, Johnstone, and Thong[64] found participating parents made more visits to health care providers. The researchers concluded that participating parents were more vulnerable than those who refused and may be viewing participation as a means of obtaining health care. The researchers urged other researchers to be careful of this coercive effect when working with vulnerable populations. Other investigators have also raised the sensitive issues of either vulnerability and powerlessness or unexamined comfort with accepting health care provider recommendations. These sensitive issues can be raised when care providers are also investigators, or closely linked with investigators, and highlight an important ethical issue for recruitment practices.[92]

<u>Research beliefs, attitudes, and experiences</u>. Both altruism and personal health benefits are factors commonly considered as motivators for research participation.[48, 54, 72, 75, 93] The desire to contribute to science and improve the health of themselves and others were commonly cited reasons for joining and remaining in clinical trials.[83] One study of recruitment and retention of African American women in Project SHARE, an HIV/AIDS medical research project conducted in Tennessee, identified that recruitment success emanated from beliefs and experiences of "getting needs met and giving to others" while retention success was about "interaction and mutual connection."[94] Supporting healthy lifestyle practices among African Americans as a group was an important stimulant to research participation among African American Adventists.[95] While helping others remained a strong incentive to participation, deriving some direct benefit for themselves or their families was also important.[75] For example, Kassam-Adams and Newman[18] interviewed 200 parents and 203 children to examine their reactions to participation in a research study of acute posttraumatic stress following a traffic-related injury. The majority of parents and children had positive reactions to research participation. They were glad they were in the study, felt good about themselves as a result of participation, and felt good about helping others.

Harth, Johnstone, and Thong[63] found parents allowed their children to participate in research for altruistic reasons or because they believed participation would help their child. Parents refused to participate because they did not have the time or desire to participate, or they were concerned about the effects of the trial medication. Psychological profiling of parents who allowed their children to participate in research indicated that participating parents were more introverted, benevolent, anxious, assertive, skeptical, and shrewd than parents who refused participation and the general population.

These positive attitudes toward research can override personal fears and apprehensions regarding research participation, even those resulting from personal experiences of racism and discrimination in health care, or those that arise from distrust of federally funded projects. For example, in one study of research beliefs among African Americans, 43% believed that research in the United States was ethical, 11% believed it was not ethical, and 43% were wary of research.[96] Dancy has developed strategies that enhance the altruistic importance of mothers as role models for their daughters' development as part of a successful recruitment strategy.[97] This approach might be employed to address a mother's fears for her baby from potential harm associated with research.[92] Balancing the perspectives of being valuable or vulnerable as a research participant is a necessary goal of effective recruitment for the National Children's Study.

Several studies noted considerable mistrust of research that was often an extension of mistrust of the researchers as well as health care system.[16, 19, 75, 98] Participants were often suspicious of the motivation of the researchers and believed research was driven by the desire for financial gain on the part of researchers and academic institutions.[16, 75] This mistrust was fostered by experiences with discrimination and previous research projects in which researchers became involved in the community to collect data, and then were never seen again.[57] Suspicion, fear, and mistrust of research have been significant deterrents to participation in research studies, especially among persons who are not white.[19]

Several inherent power imbalances and conceptual barriers promoted mistrust of research, and thus hindered the recruitment of African Americans into research projects.[97] Power imbalance barriers came about because of unequal degree of authority and influence between African Americans and health care, research, and educational institutions. Historical and current racially discriminatory social practices, such as slavery, segregation, unethical research projects, and poor health care access also contributed to these perceived power imbalances and subsequent feelings of mistrust. Conceptual barriers came about because of the way researchers and participants view one another and the research process. Researchers may have misconceptions regarding the motivation and thinking patterns of African Americans that are based on assumptions made using conceptual frameworks that have been developed and tested on the dominant culture. African Americans within a community may have misconceptions regarding research in general or a particular research study. Each of these sets of barriers contributes to mistrust by impeding communication and collaboration and could be addressed by early involvement of communities, power sharing, mutual benefit, and cultural sensitivity. As Sullivan and colleagues noted, “any project that fails to address community concerns further erodes the community’s trust.”[98]

Herring and associates[95] explored the perceptions of 56 African American Seventh-day Adventists regarding their participation or nonparticipation in past research studies through 15 key informants and 6 focus group interviews. In spite of generally negative attitudes toward research, the participants expressed a feeling of pride, co-ownership, and empowerment as a result of participating in a research study with national significance. Consistent with the findings of other researchers, the respondents who had been participants in previous studies did so for altruistic reasons. Participants were familiar with past studies, and they had a strong sense of mistrust of research and researchers. Disrespectful treatment, the lack of feedback about study progress, and no explanations for why their participation was important were reasons for disappointment in prior research participation. The researchers concluded that negative experiences and attitudes would decrease the probability of recruiting large numbers of African American Adventists into future research studies.

Corbie-Smith and associates[75] found more negative attitudes toward research than positive ones. Compared to younger adults, older adults described a more balanced view. However mistrust in the health care system and research were recurrent themes regardless of age group. Kassam-Adams and Newman[18] found age was positively associated with the increasing trust and understanding of the research process as the children aged. They also found a racial difference in the trust/information score among parents. White parents had significantly higher median scores, indicating increased levels of trust, compared to their African American counterparts.

As discussed earlier, multiple researchers have found both a pervasive mistrust in the health care system and research in general coupled with a general lack of knowledge about research and its purpose among African Americans.[16] For example, a lower percentage of African American women were aware of the availability of clinical trials.[51] African American participants in focus group studies were aware of the Tuskegee study, but harbored misconceptions regarding the exact nature of the research abuses occurring in that study. When compared with whites, there were no racial differences in the percentage of participants who knew about the study. However, African Americans were significantly more likely to believe that a similar study could occur today compared to their white counterparts.[19, 21, 49, 77]

Related to these issues of trust, African American and Hispanic American participants in several research studies expressed reluctance to participate in research involving the collection of biological specimens or administration of medications.[16, 75, 99] The analogy of being used as a "guinea pig" when participating in research was expressed in several research studies.[40, 72, 75, 93, 100] Many were also concerned about receiving differential treatment because of race. In focus group interviews with 28 women who were clinical trial participants and 34 women who had not participated in clinical trials, Brown and associates[51] noted that these women understood the concept and purpose of clinical trials, but were concerned about the possible side effects of treatments, medications, and study procedures. This concern and mistrust of research was echoed by 14 African American adults who withdrew or refused to participate in a study conducted by Gorelick and associates.[86]

Despite the profound influence of trust on health care and medical research, systematic study of trust is a newly emerging field of inquiry. Recent research has demonstrated that trust is a concept that can be measured. Hall and colleagues[101] reviewed the growing body of empirical findings regarding the causes, correlates, and consequences of trust in health care providers, medical institutions, and insurers. Several reliable and valid instruments are now available. Those measuring trust in a single health care provider remain more advanced than similar efforts to assess trust in institutions. Several studies of research participation have incorporated the Medical Mistrust Index[19, 102] and Rose et al.[103] have recently validated the Health Care System Distrust Scale. This scale includes one item on medical experimentation. Corbie-Smith et al.[74] used a questionnaire developed for the PRAISE project to assess trust, benefit, satisfaction, and burden of research participation. No conceptually based, comprehensive measure of trust in medical research is available. Kassam-Adams and Newman[18] have recently published results from using two versions of a standardized measure to assess children's [Reaction to Research Participation Questionnaire for Children (RRPQ_C)] and parent's [Reaction to Research Participation Questionnaire for Parents (RRPQ_P)] reactions to research participation. These instruments show promise and provide a basis upon which the National Children's Study could advance this important research area as part of a longitudinal study of research participation.

Implications and Recommendations for National Children's Study

Potential recommendations aimed at enhancing interpersonal trust with participants for consideration in the National Children's Study could include:

- Using face-to-face communications for recruitment.
- Knowing the target population. Have detailed information about demographics; health status and attitudes, beliefs, and experiences with health care; and beliefs, attitudes, and experiences with research:
  - Consider focusing targeted recruitment in a particular sampling area for a designated period so that recruiters can become familiar with the population.
- Listening "between the lines" for what is not said and for underlying meanings of double consciousness: assess to what extent issues of time, transportation, work, etc. are indicative of mistrust versus actual instrumental barriers.
- Tailoring a packet of community-specific strategies to address known instrumental and trust barriers to participation in each target community.
- Respecting cultural heritage and values through engaging in small acts of caring in all phases of the study—calling by preferred name including proper title and salutations without assuming the familiar, providing family-oriented gifts such as photos.
- Encouraging and providing time for participants to discuss study participation with important social networks:
  - Offering to talk with important participant social networks.
  - Creating a Sister-to-Sister or Mother-to-Mother network surrounding the National Children's Study participation, e.g. Sisters/Mothers Together Improving the Health of our Children.
- Providing child care, elder care, and transportation if needed.

- Negotiating with employers of National Children's Study participants to provide compensated leave for them to attend study visits.
- Negotiating with health care providers and social service agencies in target area to provide special access for National Children's Study participants and their families:
    - Providing a free medical visit, help in connecting with medication assistance programs, or other factors to assure that personal barriers to participation are addressed.
    - Tapping a local foundation or business to create a virtual resource directory on the National Children's Study web site for accessing a wide range of needed services and programs.
- Training staff to recognize and connect National Children's Study participants with potential health care or social service needs with the National Children's Study social worker.
- Articulating clearly the range of values and benefits as well as disadvantages and dangers of research participation.
- Using culturally specific methods, e.g. stories, when presenting both the altruistic and personal benefits as well as the potential dangers of participation.
- Conducting an extensive analysis of available measures of trust to inform longitudinal study of the role of trust in research participation for the National Children's Study.

Organizational Factors and Strategies Influencing Trust and Participation

Table 4 summarizes the relevant literature on organizational factors and strategies that influence trust and research participation among minority women and children. Key factors fostering trust include cultural sensitivity that is evidenced in multiple ways: ethnic match, organizations that foster efficiency, attend to interaction at all levels, and assure continuity, accessibility, and aesthetics.

Findings

Compatibility of participants and study investigators/staff. The impact and need for ethnic, and to a lesser extent, gender match is a persistent discourse across the literature.[16, 41, 44, 51, [56, 58, 59, 62, 71, 73, 81, 84, 104-107] Participants routinely suggest that "having someone like me" to approach them goes a long way toward engendering trust sufficient for research participation. However, they also suggest that other characteristics of the investigators and research staff—cultural competence, commitment and passion, motivation, and knowledge—are crucial and can diminish the necessity of ethnic match.[60, 85, 95, 108, 109] In the Jackson Heart Study, this was communicated as "finding a common ground" where the invitation to participate was administered in a way that, as verbalized by a potential "goes into the soul, it goes inside of you. And the fear goes away and I think that this would be the main factor in recruiting the African American community [more than the same race]."[30] Participants recognize genuine interest when they see it; it cannot be counterfeited. As such, participants can be equally suspicious of cultural "insiders" underscoring the importance of going beyond race / ethnicity when seeking compatible recruiting staff.[60]

Knowledge of and sensitivity to cultural origins and unique needs must be demonstrated for recruitment to be successful. Adubato and colleagues[90] noted that having staff who were first generation Americans and familiar with the issues facing Latino families was crucial to retention of children in a longitudinal study of lead exposure. When recruiting older minorities, Arean et al.[71] found that recruiters who were members of the target community yielded higher recruitment responses (77%) than did ethnically matched (64%) or experienced (70%) recruiters. Keller[78] and others[110, 111] have documented enhanced retention of African Americans when study protocols were implemented by trained lay health workers. Banks-Wallace et al.[81] noted the importance of attending to African American women participants' reluctance to having a white researcher as part of the storytelling intervention.

Several studies provided evidence of improved recruitment or retention when the principal investigator is of the same ethnicity[44, 57, 80, 81] and gender[69, 78, 81] as that of participants, while others[42] warned that African American researchers may be viewed as "outside-insiders" by other African Americans. Some degree of cultural synchrony was deemed important but not sufficient to recruitment success. Even when researchers were African American, differences in socioeconomic status, language, and communication, or of adoption of mainstream societal values may impact the process.[79] One way of addressing these cultural asynchronies is for the researcher to "do time" in the community and study site as a way of developing cultural competence and gaining respect.[60] Doing time may be far more important than ethnic match.

<u>Study organization and institutional climate.</u> An effective organizational structure and function is essential to study recruitment. Clearly demarcating areas of responsibility with appropriate accountability is important for any organization and is no less so for research organizations. Organizational structure and environment contribute to overall staff satisfaction and morale, both of which are readily communicated to study participants. Over a decade ago, Bland and Ruffin[112] conducted an extensive literature review of organizational characteristics facilitating effective research. They concluded that these characteristics included an organizational culture supportive of research with a productive, respectful group climate, leadership by a skilled scientist, participative governance, a flat and decentralized organizational structure, open communications, adequate resources to accomplish the research targets, and conscious socialization / training of new members and staff. There is little to suggest that these factors have changed in the past decade. An organization that supports and provides forums for regular discussions about roles, policies and procedures, and ethical and emotional issues raised by the day-to-day work of participant recruitment and retention contributes to preventing burnout, sustaining organizational affiliation, and maximizing participant relationships.[71, 113, 114]

Organizational commitment to assuring sufficient resources, particularly staff, for recruiting African Americans was emphasized by several authors. Notably, the Women's Health Initiative identified the increased cost in both staff, time, and materials (mailings) to recruit minority women's participation.[43] The Jackson Heart Study reduced the target recruitment size for the cohort and included a volunteer sample, hired 7 additional recruitment staff, and extended the time for recruitment by 6 months to meet recruitment goals. Each of these elements substantively increased the cost of recruiting the cohort.[39]

Hiring from the community and providing ongoing investigator and staff training, particularly in areas of cultural sensitivity, were consistently discussed.[43, 57, 58, 60, 73] Several papers stressed the importance of historical cognizance, investigator self-reflection regarding racist practices, and extensive staff training that goes beyond the study protocol to include nuanced ways to approach minority populations.[42, 113] The Framingham Study, one of the longest ongoing epidemiological studies with over 50 years of experience in retaining what is now a biethnic cohort, has attributed much of its successful cohort maintenance to staff training and attitudes.[115] The Jackson Heart Study developed an extensive training program for recruiters and other staff that included social, cultural, and ethical foundations of research participation; communication and cultural sensitivity; as well as didactic and practical training in protocol implementation. In addition, ongoing weekly debriefing sessions were held to address day-to-day issues, provide counsel and support, and accomplish ongoing training with opportunities to critique interviewing techniques.[39]

How the community viewed the research institution was another critical factor identified in the literature.[58] Levkoff and colleagues noted the importance of "matching" between research institutions' and communities' perspectives. Large, academic institutions were often perceived as a power elite, not involved or invested in the overall welfare of the community.[44] In one study of Latino women, the university affiliation of the study served as a positive influence on trust and study participation.[116] Organizations that consistently communicated a commitment to improving the health status of African Americans might anticipate more success.[80] The planners for the Jackson Heart Study selected a consortium of collaborating organizations comprised of 2 historically black colleges and universities (HBCUs) and 1 medical center with a mission to improve the health status of all persons in the state, especially the underserved and minorities, to carry out the study. Similarly, the National Children's Study planners should carefully consider intentional strategies for including HBCUs and other well-respected ethnic institutions as part of the study organization at every opportunity. Not only does such a strategy enhance participant trust, but it provides important opportunities for cross-institutional collaboration that confronts institutional racism in daily operations.

Continuity. The Framingham Offspring Study,[115] for example, credits much of its success in retention from one generation to the next to dedicated and caring staff who stayed in contact with participants, becoming a part of each other's lives, not just researchers and researched. Longitudinal studies have the burden and the opportunity to develop lasting and meaningful bonds with participants and the community that make a difference in ongoing study participation. As one potential Jackson Heart Study participant so cogently stated:

> …you couldn't expect me to leave the comfort of my house and come to the hospital to get stuck, probed or pressure taken or whatever and then say "OK. Thank you

> very much. Have a nice day." I mean it would have to be…a type of relationship with the people that is conducting the study…over a period of time.[30]

When the same staff continued to contact participants, both retention and the quality and completeness of data collection were enhanced.[62, 87, 117] When participants missed appointments, personal follow-up by bilingual study staff was an important strategy for a longitudinal study of Latino family caregivers.[118] In the New York Angler Study,[62, 87, 117] a longitudinal study of children born to mothers enrolled in a prospective pregnancy study with similarities to the National Children's Study, having a consistent study team contributed to parents' willingness to enroll their children for continued observation of the effects of pesticides for two additional years after birth. Providing ready access and the availability of ancillary staff, such as social workers, to assist with health care access and other social issues can improve retention as well.[90, 119]

Some studies have provided names and personal telephone numbers,[85] or established toll-free[43, 54] or beeper numbers[94] so that participants can contact them at any time. Others have user-friendly web sites where participants can obtain information quickly—a strategy that is increasingly important as technological access to information becomes the norm.

Accessibility and aesthetics. The environment of the data collection site can go a long way toward promoting or dissuading ongoing study participation. An environment that is respectful of people and their time, caters to their sensibilities, and is openly hospitable communicates that the people who come are worthy and cared about.[117] In addition to being clean and comfortable,[94] data collection sites that were located in the community where participants lived and worked enhanced study participation.[50, 57, 62, 81] Often, for the ease of the researchers and the demands of the protocol, minority participants are expected to travel to majority institutions or other venues which serve as data collection sites. Assuring data collection sites that are located within minority communities will be an important consideration for enhancing trust in the National Children's Study. When possible, combining data collection with postnatal and well-child visits was suggested by the *White Paper on Recruitment and Retention for the National Children's Study*[120] and we would concur with that recommendation. Mechanisms to enhance accessibility, being as "user-friendly" as possible, will be important to assuring participation of the 21-year term of this study. Each of the over 100 National Children's Study sites across multiple states will need to attend to aspects of location that reflect the cultural and geographic realities of that site.

The location of the Jackson Heart Study in the heart of the African American community in a shopping mall refurbished and revitalized for providing health care resources to the community has been a positive influence. Also, we intend to offer off-site and in-home data collection in the second exam for persons who cannot travel to the examination center site.

Implications and Recommendations for National Children's Study

Potential recommendations aimed at enhancing organizational and study institutional trust for consideration in the National Children's Study could include:

- Carefully attending to staff selection and training:
    - Developing job descriptions with position qualifications that reflect prerequisites for engendering personal trust in the potential National Children's Study cohort.
    - Including role plays of selected "real life" situations based on building trust in staff applicant interviews.
    - Hiring staff who are "people persons" dedicated to study and its importance, are friendly, sincere, and personable.
    - Hiring recruitment and clinic staff from the African American and minority community of the study site could provide a context in which participants might be more comfortable asking questions and expressing concerns.
- Assuring the presence of minority investigators and staff in key leadership positions and that information on study governance and decision making is transparent.
- Creating an organizational structure for the work of the National Children's Study and its individual sites that recognizes and respects participation across institutions as well as with the community as co-investigators.
- Providing adequate budget to accommodate the increased staff, resources, and materials costs of recruiting African Americans.

- Providing ongoing recognition and appreciation of staff and investigator contributions to study success and progress including appreciative mementoes, study-wide gatherings, and incentives over the course of the study, not just as a one-time thing.
- Conducting ongoing training of staff with regular debriefings of experiences and successful strategies which would expand their individual skills.
- Employing ethnic (gender, age) matched staff for initial and ongoing participant contact whenever possible, including, for example:
  - Sending teams of recruiters of mixed ethnicity, gender, or age. When not possible, sending recruiters with different characteristics from the original to assure that decision not to participate was not based on mismatched messenger.
- Hosting regular National Children's Study Research Days where recruiters and other study staff contribute their collective wisdom to the larger National Children's Study team of investigators and staff.
- Providing clear identification of all staff, e.g.,
  - Considering common clothing for recruiters with study logo (potentially created by the community).
  - Wearing picture name badge with institutional and study affiliation visible.
- Providing an organization that lives up to its promise of respecting people's time.
- Assuring collaboration among the parent institution for individual National Children's Study sites and NIH agencies that continuously attends to any fears and concerns among participants regarding academic health care institutions and federal agencies.
- Recognizing communal participation taking every opportunity to express gratitude for participation, providing appreciative mementoes and incentives over the course of the study, not just a one time thing, e.g.,
  - Sending birthday, Kwanzaa, or other holiday cards to all study participants annually as a remembrance of special times of the year and an act of appreciation for their involvement.
  - Sending thank you letters following each study contact expressing appreciation.
- Assigning dedicated study staff to particular participants to engage in ongoing contact and follow up.
- Following up with study participants and contacts with study satisfaction questionnaires, the content of which is co-designed with the participants.

- Providing mechanisms for ongoing participant-staff communication, e.g.,
    - Creating a study “hot line” where any compliments, complaints, or suggestions can be addressed.
    - Hosting a regularly scheduled “chat room” to entertain issues and concerns.
    - Featuring National Children’s Study researchers/staffs and participants (with permission) in National Children’s Study newsletters.
    - Sharing in meals and other community activities to nurture connections and create study bonds.
    - Engaging in ongoing intercultural dialogues among minorities and whites, researchers and researched, and the community at large.
- Assuring that National Children’s Study sites are aesthetically appealing. Include culturally relevant reading materials and art work, keep site rooms clean, and have well appointed facilities:
    - A building that is warm and welcoming.
    - A clinic site that is designed for children and their needs while waiting for study visits.
    - An environment that welcomes suggestions and comments by placing a suggestion box in a prominent site to encourage participant comment.

Protocol Factors and Strategies Influencing Trust and Participation

Table 5 summarizes the protocol factors and strategies influencing trust and research participation among potential National Children’s Study minority participants. Emphasis was placed on research designs that include multiple methods, attend to retention as well as recruitment, and employ theoretical models that enhance inclusion of minorities. Priority was also given to protocols that employ consent strategies that provide full disclosure, flexible and creative approaches to overcoming cultural and personal barriers to research participation, and tracking and feedback systems that assure ongoing information exchange. The *White Paper on Recruitment and Retention for the National Children’s Study*[120] has previously addressed study design issues related to method of recruitment for women and children, respondent burden, incentives, and participant motivation and knowledge. In general, this report has recommended several important protocol implications for the National Children’s Study:

- Face to face interviews and in person visits.
- Well-communicated incentives.
- Clearly articulated study expectations and benefits, including contributing to the “good of mankind.”
- Maximum flexibility in time and place of study visits to accommodate family issues
- Managing participant burden.
- Ongoing feedback to participants.
- Carefully developing participant tracking / tracing systems.

This section will build upon these recommendations by focusing on the impact of these factors on trust among African American participants.

Findings

Research design. The recruitment and retention literature consistently emphasized study design issues including the sampling design and site of recruitment, method of approaching participants, inclusion and exclusion criteria,[43] the invasiveness of study protocol / data collection methods,[121] as well as perceived or actual participant burden. Each of these aspects of study design can build or erode trust in the participant group. Suspicion and mistrust were heightened by what may be perceived as exclusionary sampling criteria, particularly when randomization procedures were used. For example, the Jackson Heart Study found that continuing to use an exclusive random selection process for community participants was a deterrent to trust. By including a volunteer selection process that matched participant characteristics with those of the random selection process, trust was enhanced and recruitment targets were more easily attained. As other studies with women have found, less restrictive recruitment approaches might foster higher retention rates as a result of increased trust. [79] For example, the Right From the Start study, a community-based study of early pregnancy, employed a multifaceted approach including public and private prenatal clinics, as well as direct community contact, in order to achieve ethnic and socioeconomic balance.[54] These issues have been extensively reported for the National Children’s Study in the *White Paper on Sampling Design*.[122]

Face-to-face contact has been repeatedly favored by African Americans over telephone contact from unknown persons.[68, 73, 123] Culturally insensitive data collection instruments and excessive participant burden—long and repetitive clinic sessions, inclusion of extensive biological samples—raised multiple issues of particular concern to African Americans regarding use and control of specimens, particularly genetic data. Related to these issues of trust, African American and Hispanic American participants in several research studies expressed reluctance to participate in research involving the collection of biological specimens or administration of medications.[16, 22, 99]

The longitudinal study design of the National Children's Study coupled with extensive data collection in multiple domains over such a significant number of years presents unprecedented challenges for recruitment and retention. Having a well-articulated plan for both recruitment and retention at study outset is imperative. The literature is replete with strategies to enhance recruitment, often undertaken without a comprehensive plan. Several recently published models of research recruitment with African Americans, as well as the model used for this *White Paper,* offer frameworks to guide development, implementation, and iterative evaluation of recruitment and retention protocols. It should be considered by the National Children's Study. Using these conceptual approaches to designing culturally and community responsive research designs offers much promise for improving research participation in minority populations.[44, 48, 58, 82, 124, 125]

Table 2 summarizes the major components of each of these conceptual models of research recruitment and retention. A key feature of all these models is a multifaceted, often multimethod, approach that uses many strategies simultaneously. The models vary in the levels of community engagement. Several models implement community based participatory research frameworks while others focus on social marketing, health services utilization, or health care access frameworks. For example, Ashing-Giwa[126] describes a culturally responsive model similar to the POPCI model used in this report. In their model, preinvestigational factors include aspects of personal (participant) and sociopolitical, cultural and community context (community involvement). Investigational factors include the specifics of research organization and study protocol. Levkoff and colleagues[44, 127] have similarly identified a model that calls for a match between minority community and researcher goals. They specify a set of macro (institution/community), mediator (gatekeepers/research team), and individual (participants/interviewers) barriers and facilitators for each partner and identify trust-building strategies for enhancing this "match." Likewise, Wyatt and colleagues[82] have specified a community driven process model for engaging communities as co-investigators at all levels from preinvestigational, investigational, and evaluation / dissemination.

Models that employ social marketing, health services research, or health care access frameworks can be used in situations where extensive community engagement is not anticipated or as a component of more broad-based participatory action models. These models offer the advantage of providing specific intervention strategies that can be incorporated within a wide variety of conceptual approaches. For example, Nichols et al.[62] employed a 6-step social marketing framework that included the following steps:

- Defining and identifying the target audience
- Developing the research intervention
- Managing the price
- Improving accessibility
- Promoting the study
- Working with partners

Similarly, Wisdom and colleagues[128] describe the integration of 2 theoretical models: a 5-component interactional model (caring, reciprocity, trust, sensitivity, and involvement) with a model for access to care (acceptability, affordability, availability, accommodation, and accessibility) to guide specific recruitment activities within each domain.

Few studies have included rigorous evaluation of conceptual approaches, and no studies comparing results from more or less community-engaged frameworks have been conducted to date. It is clear that such studies are needed. The National Children’s Study is uniquely situated to include such comparative and evaluative studies as part of the overall research plan, thus providing definitive information on the variable response to implementing and evaluating theory-driven approaches to recruitment and retention in culturally and geographically diverse samples. The merit of this potential contribution could equal the scientific outcomes of the National Children’s Study.

Consent. Issues of informed consent loom large for this and most longitudinal studies of such breadth. Assuring that potential participants fully understand the assurances of confidentiality, as well as the balance between risk and the scientific interests of research that is done for the benefit of others, and providing protection for the interests of the individual is a heavy responsibility.[129] Courtney and Marks[130] in a white paper prepared for the National Children's Study, have previously discussed a number of such issues. Issues not previously addressed in this prior review relate to the largely overlooked extent of hidden illiteracy which compounds the consent burden, the level of disclosure, and the type of consent, all of which have relevance for building trust.

Twenty-two percent of adults in the US are functionally illiterate, and another 27% have marginal literacy skills.[131] Difficulty with general understanding of the informed consent process has been noted in the literature on African American participation.[75] In addition to general lack of knowledge regarding research process, minority participants in several studies had a lack of understanding of the informed consent process.[16, 27] One of the participants in a study conducted by Corbie-Smith and others[15] summarized this idea by saying that there was a difference between "knowing" and "understanding." Other participants believed the informed consent process was designed to protect the researcher and institutions rather than the participants; they expected dishonesty and nondisclosure of research risks. Many believed that signing such a form was equivalent to relinquishing their autonomy. To overcome these barriers, study participants suggested ensuring potential participants had full knowledge about research procedures and the exact nature of their participation: this assurance would increase trust and the likelihood of research participation.

Methods of information presentation are similarly important trust issues. Issues of health literacy can present difficulties with obtaining consent and collecting data. Participants wanted to receive the information from multiple points of view, and they wanted time to talk with friends and family members about the information prior to giving consent. Enhancing participant "understanding" is thus likely to require more time for explanations and allowing for potential consultation with family and social networks, use of multiple methods of information delivery, and culturally appropriate language.

Repeated contacts were not uncommon before a participant agreed to participate.[79] Making consent forms comprehensible, with careful attention to reading level, will be an imperative for the National Children's Study. We recommend including community members from key National Children's Study sites for the development of language and testing forms to ensure information clarity in advance of their use. This is particularly important for minority participants and for those whose primary language is not English.

Table 2. Conceptual Models of Recruitment and Retention

Citation	Focus		Major components	Reported use	Comments
	SM[†]	CD[†]			
Ashing-Giwa[126]		√	Culturally Responsive Model for Research Design: *Preinvestigational* - sociopolitical context - cultural context - network / community context - micro level or personal *Investigational* - research purpose - conceptual frame - methods and procedures - data safety and monitoring - staff training - instrumentation - conclusions - dissemination	Model synthesized from 10 years of qualitative and quantitative investigations with multiethnic female breast and cervical cancer survivors (~1250)	-Model recognizes the increased demand on investigatory team to create effective community collaboration, culturally competent research staff, and community forums for research dissemination -Stresses that culturally responsive research requires multiple methods of data collection
Levkoff et al.[44, 127, 132]		√	Matching Model--3 levels of barriers and enablers for ethnic minority & and research group: *Macro* (community agencies / academic institutions) - barriers - enablers	Used to recruit minority elders for participation in studies of the 6 NIA funded Exploratory Centers for Minority Aging and Health Promotion	-Model posits that match between goals of ethnic minority community and research community lead to recruitment success; mismatch to failure. -Incorporates elements of cultural and structural styles and history of both partners to identify group specific barriers and enablers for research recruitment

Table 2. Conceptual Models of Recruitment and Retention

Citation	Focus		Major components	Reported use	Comments
	SM†	CD↑			
			Mediator (gatekeepers & health care providers / Research team) - barriers - enablers *Micro* (participants / interviewers) - barriers - enablers		
Nichols et al.[62]	√		6 steps based on 6 "P"s of social marketing: 1. define target audience (Participant) 2. develop product (Product) 3. Manage the price (Price) 4. Improve accessibility (Place) 5. Promote the study (Promotion) 6. Work with partners (Partnership)	Used to recruit 1222 caregiver/ care recipient dyads in multi-site study of interventions with Alzheimer's caregivers (REACH study)	-Social marketing principles used to map out recruitment steps and plan for resource allocation. -Indicated that these principles should be combined with consumer-centered models for maximum effect
Sasso et al.[133]		√	"Cube" model is shown as a 2x 3 cube that depicts 3 elements of community research: *Methods* - qualitative - quantitative	Proposed for use In: -conceptualizing and designing community research projects -identifying limitations in a	-Purpose was to provide conceptual and methodologic framework that is culturally anchored and ecological-contextual. -Intended to provide guidance for incorporating "cultural complexity" into community studies. -Stresses that ethnic-cultural community be

Table 2. Conceptual Models of Recruitment and Retention

Citation	Focus		Major components	Reported use	Comments
	SM†	CD‡			
			as basis for considering: *Cultural Complexity*: - sub-cultural (street) - ethno-cultural (community) - a-cultural (ethnic gloss) *Type of Questions*: - Descriptive /Epidemiological (needs assessment) - Etiological / Explanatory - Prevention / Treatment (program evaluation)	study	understood in larger context of society where community is embedded (social ecology)
Wisdom et al.[128]	√		*Interactional*[1] -caring -reciprocity -trust -sensitivity -involvement *Access to Care*[2] -acceptability -affordability -availability -accommodation -accessibility	African American clinical trial with Type 2 diabetes	Report of recruitment using a combination of 2 theoretical models that provided *a priori* guidance to developing strategies for recruitment and retention

Table 2. Conceptual Models of Recruitment and Retention

Citation	Focus		Major components	Reported use	Comments
	SM[†]	CD[‡]			
Wyatt et al.[30, 39, 82]		√	POPCI Model *Participant* *Organization* *Protocol* *Community Involvement*	- Synthesized from literature & interviews with investigators of select NHLBI-funded studies conducted with African Americans - Used to inform study of barriers and facilitators to research participation in African Americans	-Descriptive model that includes Factors and Strategies with subcategories of barriers and facilitators for each -Provided basis for developing a survey to assess each element of the model
			Community Driven Model comprised of 3 overall patterns: *Safeguarding Political and Moral Concerns* *A Community Driven Model for Recruiting and Retaining Research Participation* *Growing, Cultivating and Building Community Partnerships*	-Used to recruit ~5300 African Americans in the Jackson Heart Study	-Process model where community members are engaged as co-investigators to participate with researchers in all levels of the study—preinception through dissemination -Content of the model is defined by implementing the process of engaging co-participation in all aspects of research project in particular community

[†] SM- Social Marketing, Health Services or Health Care Access; [‡] CD- Community and/or Culture Driven

[1] Hautman MA, Bomar P. Interactional model for recruiting ethnically diverse research participants. J Multicultural Nursing and Health 1995. 4:8-15.

[2] Penchansky R, Thomas JW. The concept of access: Definition and relationship to consumer satisfaction. Ked Care 1981, 19(2):27-40.

Studies that include biological and genetic components raise additional issues of disclosure that require a great deal of sensitivity. At what point are the best interests of the group or individuals studied compromised? Is it really in the best interest of African Americans to know if genetic differences form the basis for disease development over a life course? Experience reported in the NHANES III documents that women and African Americans were least likely to consent to having their blood samples stored in a repository for future genetic research.[134] Most studies report that participants want clear information regarding genetics, its risks, and how genetic information such as cell lines will be protected in and of themselves, as well as how information learned will be kept sacrosanct and unavailable to insurance companies or others who might use it to the detriment of the individual. The CDC has provided guidelines and consent templates for integrating genetic research into population based studies.[135] Such issues must be continually negotiated by fostering open dialogue.

Many studies, including the Jackson Heart Study, have obtained a Federal Certificate of Confidentiality to protect researchers, within the limits of the law, from being compelled to identify participants or disclose information. However, even with such safeguards in place, there are potential limits to confidentiality that can influence trust if they are not disclosed to study participants. Given the nature of the National Children's Study and its likely participants, potential limits to confidentiality include evidence or disclosure of child abuse or intent to harm oneself or another. While such disclosure may reduce the initial recruitment of participants, it is likely to increase the trust in the researcher and favorably impact retention. Haggerty and Hawkins[136, p 511] provided potential language for inclusion in consent forms to assure that consenting parents and assenting children/adolescents understand these limits:

> If you talk about your child/children being harmed, if you are under 18, living at home and being harmed by a parent, or if you talk about harming yourself or another person, the study [personnel], working with your [health care provider], must report this. This reporting is required by law. This is the only time that information from the study must be shared with anyone outside of the study.

Passive versus process consent has received some attention in the literature and was addressed for the National Children's Study.[130] As part of the consent process, the Jackson Heart Study has taken several bold steps intended to address issues of trust. First, we instituted a signed investigator pledge to the participants. We know of no other study that has used such an explicit reciprocal pledge as part of the consent document. Second, we have made explicit the ongoing process nature of consent by including a review of current consent status as part of each subsequent examination. Participants are asked to affirm their current consent status, or to modify it in accordance with current preferences.

This stance emphasizes the ongoing voluntary nature of participation and the right to change the level of consent at any time. By focusing on consent as a process, the intent of the investigators to abide by participant choices regarding their study data is made transparent. The National Children's Study might consider implementing a similar approach. The National Children's Study "process" consent approach must also include a mechanism for assuring that children enrolled at birth have a developmentally appropriate level of understanding of their participation in this long-term study. One recent qualitative study explored the experiences of children's and adolescent's participation in research. Their findings regarding the role of important relationships with older adults—parents and researchers/health care providers—were congruent with a "family rule" where consent is regarded as a shared phenomenon between participating children/adolescents and their families. Implicit and developmentally based negotiations between child and parent both include the child in the decision making and recognize her/his right as an active participant.[111]

Accommodation to participant. Several studies have highlighted the importance of specific and creative strategies aimed at accommodating personal barriers to participation. Offering transportation, child care, nutritional and appealing snacks or meals, and providing social services assistance were among the many strategies used. For example, the Coronary Artery Risk Development in Young Adults (CARDIA) successfully used frequent contact, such as telephone reminders the night before, and, occasionally, wake-up calls the morning of the scheduled visit, to reduce attrition.[137] The time between initial recruitment and the scheduled study visit was kept to a minimum and daily appointments were overbooked to accommodate no-shows. The Jackson Heart Study has provided social work services and referrals for health care when needed.[39] An extensive community referral network was developed with providers who are willing to see Jackson Heart Study participants at reduced cost when they have no health insurance. Also, a community resource directory has been developed to provide readily available information on a variety of community resources for health and wellness.

Recognition of cultural heterogeneity within African Americans and other minority groups means that there is no “one size fits all” method of accommodating participant needs. For example, one study found that having data collection sites in churches located in the community was highly successful.[138] Others found that church-based strategies were ineffective[71] and presented important challenges emanating from suspicion of research and the churches being overburdened as too many researchers consider them “ideal” sites for African American research recruitment.[139] Senn and colleagues[87] found that using in-home data collection in a preconception prospective pregnancy study fostered ongoing study involvement among parents and children. Individualization of strategies that accommodate participant needs is a key strategy, particularly for studies with potentially changing participant and environmental conditions.[113] Designing the study so that participants can complete the protocol, rather than blaming attrition on participant factors for their failure, will be the challenge for the National Children’s Study. Roth et al.[94] challenge researchers in longitudinal studies with women to recognize that while using creative strategies to overcome participation barriers, simply providing transportation or child care will not be enough. They found that ongoing opportunities for developing close relationships with researchers were requisite to retention.

Quality assurance, tracking systems, and participant feedback. Participants are keenly aware of issues related to study quality and feedback. Policies and procedures for data collection, handling, and sharing, as well as assuring data integrity and confidentiality, requires careful planning.[140] The advent of large studies with multiple sites (among which the National Children’s Study may be the largest) coupled with the technological advances in data sharing, compound these issues. Having well-developed procedures and protocols in place at study start is the ideal, though this is often difficult in large studies such as the National Children’s Study, where practices will evolve as the study progresses.

Assurances and evidence that the study does monitor itself and has a rapid response time to improve quality are paramount to study success. A written quality assurance plan aimed at preventing data problems and preventing questionable practices is an essential element of engendering trust.[141] Though participants may not be directly aware of all the processes in place, staff has the opportunity to communicate procedures that imply ongoing quality control. For example, if a participant happens to be selected for a replicate study, staff can identify the importance of checking the data for accuracy. Likewise, tape recorders may be used to record interviews for data quality and training purposes. Displaying study staff credentials and certification for performing examination procedures and interviews in prominent locations at data collection sites provides assurance of competence. Having community members as part of key study committees provides them the opportunity to observe first hand and report back to their constituency the efforts that the study is employing to assure quality. As well, the Jackson Heart Study includes members of the community as part of the routine quality assurance observations of clinic procedures providing another layer of community involvement in the conduct of the study.

Multiple studies have identified the importance of ongoing monitoring and a tracking system that provides weekly assessment of the recruitment effort with indications of problem areas.[142] This monitoring requires substantive commitment on the part of study investigators to collect, analyze, and respond to tracking data in a timely fashion.[143]

A system for tracking/tracing participants who move and for converting nonresponders is an important consideration for ongoing retention. Pierce and Hartford[120] provided a comprehensive discussion of these issues in their white paper for the National Children's Study. Experiences from the Jackson Heart Study and the ARIC study give additional support to the variety of techniques and approaches identified in their review, including:

- having multiple methods of contact for each participant and updating contact information regularly.
- including "Forwarding Address Requested" on all outgoing mail to participants.
- having the same staff person contact participants.
- following a systematic procedure that includes differential approaches for those the staff is 1) unable to contact, 2) unable to complete, 3) unable to locate, and 4) those who refuse further participation.[118]

Informative feedback has been reported as one of the most important strategies for retention in longitudinal studies.[144] Newsletters are commonly used to report emerging findings and maintain a link with participants between study visits. Rapid turnaround time on obtaining relevant results of individual study data collected is likewise important.[51] Providing feedback to participants and their health care providers on study results needs to be timely and informative. This was a particular issue for the Jackson Heart Study. Results were compiled from multiple reading centers across the country. Achieving results reporting mechanisms that accommodated time needed to complete and transfer data to the Coordinating Center; collated results into a user-friendly format; and distributed them to participants and health care providers proved a challenging task.

Implications and Recommendations for National Children's Study

Potential recommendations aimed at developing a protocol that engenders participant trust for consideration in the National Children's Study could include:

- Identifying and using a specified conceptual model to guide study and recruitment methods
    - Assuring that the recruitment protocol includes extensive sociodemographic tracking data on participants, nonparticipants, and drop-outs.
    - Collecting multiple methods of contacting participants with specific tracking to prevent loss to follow up.
- Sampling and eligibility criteria as inclusive as possible for study purposes.
- Using multiple methods of sampling as recommended by the white papers on *Sampling Strategies for the Proposed National Children's Study,*[145] *Advantages and Limitations of Alternative Sampling Methods for the National Children's Study,*[146] and *Evaluation of Sampling Design Options for the National Children's Study.*[122]
    - Advertising in community
    - Health care provider identification and referral
    - Cluster random sampling with door to door contact
    - Snowball sampling
- Including culturally appropriate language in data collection tools.
- Including language collaboratively developed by community members and investigators in consent materials that clearly communicates all components of informed consent.
- Obtaining a Certificate of Confidentiality to provide legal protection preventing researchers from releasing private participant data.

- Creating a video tape or photo novella consent which might help improve understanding of the National Children's Study and generate higher levels of comfort with participation:
    - Including an investigator pledge to study participants.
    - Assuring mechanisms for continuous negotiation of consent across the study such that participants are totally comfortable that they have full control over the use of their study samples and materials.
- Implementing a participant friendly protocol:
    - Offering flexible scheduling.
    - Making reminder calls in advance of clinic visits.
    - Providing child care.
    - Providing options for site of data collection whenever possible.
- Providing meaningful and well-timed incentives to study participation, whether monetary or not:
    - Considering carefully the recommendations emanating from focus groups conducted for the National Children's Study where participants identified incentives that would have relevance for them across the years of the National Children's Study.
- Holding NICHD site visits to National Children's Study sites that are open to the public, announced to the community in advance, and scheduled in locales to accommodate community attendance.
- Conducting weekly tracking sessions to monitor recruitment data with quick response to identified issues.
- Providing timely and ongoing feedback to participants regarding their results and findings:
    - Mailing a study newsletter on a quarterly or semiannual basis to update participants on findings and study information.

Community Involvement Factors and Strategies Influencing Trust and Participation

Table 6 summarizes the community involvement factors and strategies influencing trust and participation among minority women and children. As Hill and Weiss note in the preface to the NIH conference on Health Behavior Research in Minority Populations: "It has become evident…that research endeavors must give special consideration to the unique social, cultural, and economic milieu of the community to be studied, and that understanding the lifestyle, needs, and desires of the community is essential."[147] This theme was reiterated across the recruitment literature. Positive and effective strategies that promoted community mobilization and partnership, the translation of research findings to benefit the community, and the social context in which the findings were disseminated were critical for the promotion of trust that enhanced recruitment. While it is important to recognize that there is no "one size fits all" model for engendering community involvement, this review does highlight effective and ineffective factors and strategies that have been used in a variety of settings. This information can be used to design strategies tailored to each unique National Children's Study site.

Findings

Community mobilization. The lack of knowledge regarding research among community members presents a significant barrier to participation.[51] Nichols and her associates[62] stressed the importance of using a social marketing approach when recruiting participants for research studies. Aspects of social marketing that were most pertinent to this discussion of community mobilization were defining the target audience and promotion of the study. Knowledge of the audience was crucial for designing effective promotional activities to reach ethnic minority women and children. Promotion involved a combination of advertising, media relations, personal selling, and entertainment to provide the community with information that increased awareness of the particular research project or research in general.

Researchers have successfully used strategies such as the involvement of key community gatekeepers as study advocates, the proliferation of study and recruitment information in culturally appropriate venues, outreach presentations by trusted community leaders, and face-to-face contacts to inform the community and encourage research participation.[51, 61, 81] Outreach efforts that were most effective in reaching and recruiting persons who are members of racial and ethnic minority groups were designed to be sensitive to the culture, traditions, beliefs, practices, and lifestyles of the target population.[125]

Researchers with the Women's Health Initiative used mass mailings and media as the primary recruitment strategies as well as study orientation sessions in which they provided women with detailed information about the study.[51] However, to increase the pool of African American and Hispanic participants, the researchers used additional, culturally based strategies such as targeted mailing lists, endorsements from community leaders and well-known minority elected officials, and health messages specific to targeted minority groups.

Gilliss and associates[68] used printed materials such as brochures, fliers and advertisements, and radio and television public service announcements to reach large numbers of women, but they found direct face-to-face contact to be an especially effective method of recruiting African American and Hispanic women. Interestingly, there were no significant differences among racial groups in the retention rates based on recruitment strategy.

Blumenthal and associates[56] found no improvement in participation rates based on the fact that their study was being conducted by well-known community organizations and institutions. However, taking the project directly to the community with door-to-door recruiting and approaching women in laundromats and beauty salons was more effective. Likewise, Sixsmith and associates[148] found face-to-face contact in the form of street interviews to be a successful strategy for recruiting participants for focus groups.

Other strategies that have been used to increase visibility and trust within the community include participation by researchers and staff in community organizations, meetings, and activities; working within existing social networks to provide needed services and information about the study, and establishing a trusting relationship with family members, health care providers, and community leaders such as ministers, council officials, local project leaders, educational providers, and tenant or neighborhood association presidents.[41, 56, 125, 148, 149] Sixsmith and associates[148] interacted with various subcultures within the community, such as drug users, homeless persons, and gang members, in order to recruit a diverse sample of the community.

<u>Community partnership</u>. With each of the previously mentioned methods of community mobilization there is an inherent power imbalance that can continue to impair equal partnering and trust in research.[95, 99] Furthermore, researchers must often overcome distrust in local academic institutions which may have been fostered by previous researchers who focused on the research alone without establishing long-term relationships within the community.[98, 125, 150, 151] The most innovative researchers have moved beyond “advisory”

functions to generate true partnerships where communities actually define research agendas and academic scientists collaborate with them in carrying out these projects.[151] The researcher seeks the advise of the community prior to designing the study and actively collaborates with the community in determining the goals of the study, the design, analysis, and use of the findings.[150]

This rapidly growing body of research literature using community-based participatory research has been extensively reviewed for the National Children's Study by Alakoye[152] and Myers.[153] In general, this literature frames research practices to extend the usual model of science and scientist-driven research, in which communities and participants are recipients, to one in which community members and scientists are "collaborators" with co-participation in defining research agendas. However, it is important to note that many of the community-based strategies being proposed to increase recruitment of African Americans and other persons who are members of racial and ethnic minority groups into research studies were used with much success to recruit participants into the Tuskegee study.[15]

Hatch et al.[150] discussed several methods of enacting community partnership. In the least interactive mode, researchers consulted persons who work in the community to gain insight into the needs of the community and means of contacting and interacting with key community members. These initial contact persons were often at the periphery of the community's cultural system because they do not live among the target group. Among the more interactive methods of building community partnership is the use of community research boards, often called "advisory boards" or CRABs (community research advisory boards). Researchers solicited the endorsement of influential leaders such as ministers, physicians, politicians, as well as institutions such as fraternal organizations, and HBCUs to engender support for the research within the community.[95, 99, 125] However, the researcher maintains total control of the study and the communities, as well as the leaders, take on a passive role of advising. Burrus et al.[154] and Sambo et al.[155] both report incidents in which members of the community advisory board were instrumental in dispelling rumors that could have hindered participation. In some instances the advisory board participates in hiring of interviewers, outreach workers, and screeners, but the advisory board has no input into the design of the study or the interpretation of findings.

Dancy et al.[97] provide a description of engaging an African American community in a collaborative partnership to address health disparities by developing a coalition of entities, including professionals serving minorities, religious leaders, and community residents. Furthermore, some Native American communities have demanded this level of control when working with researchers.[156] Working with the Indian Health Service, these communities have formed agencies that control access to the population, ensure that the research addresses local priorities, claim ownership of the data, and approve publications prior to dissemination.

Throughout this literature, the church was often imputed as an effective avenue for gaining entry into the African American community. African Americans may be more likely to participate when churches provide the recruitment venue, however, participants may feel obligated to take part because the project was supported by the church.[157] Meaningful involvement of the church community and integration of church members as part of the research staff have been identified as essential strategies for motivating research participation.[95]

This type of community involvement presents a challenge to the researcher as well as the community. Researchers, authorities on the theories and methods involved in the research process, are challenged to protect the rigor of the research process so that results obtained will be valued by the scientific community. The community members are authorities on the conditions that affect their lives. They are challenged to select research projects that are relevant, assure the safety of participants, prevent the dissemination of damaging interpretations of the findings, and establish an infrastructure to maintain long-term benefits to the community.[69, 150, 156]

Regardless of the level of community involvement, several researchers in this review stressed the importance of an optimal match in perspectives in which communities and researchers perceive a mutual benefit through collaboration.[44, 95, 98] Both parties must engage in a useful exchange of information in which community leaders relate their most pressing needs and researchers use their skills and knowledge to design research projects that will address these concerns in a respectful manner.[156] The researchers must commit to establishing and maintaining a long-term investment in the community.[95, 98, 148]

Researchers can promote an exchange of services between the community and the university by acting as advocates for the community within local academic institutions. Interventions such as health promotional education, physician examinations, and provision of scholarships promote community support.[154, 155] The community can also benefit from contacts that researchers bring that facilitate communication among various community organizations and community members.[148]

The Jackson Heart Study has developed multiple strategies of community partnership, including assuring voting membership of community representatives on all major study committees, especially the Steering Committee, Genetics Committee, and Publications Committee. While these methods are effective when compared with traditional recruitment strategies, they are time and resource intensive, requiring long-term commitment of investigators and funding sources. In spite of the costs, however, the importance of finding links within the community targeted for research cannot be overstated. The input of people within the community regarding the best way to recruit minority participants is vital.

Translation of research findings. An ongoing concern for minority communities has been their use for knowledge creation without returning that knowledge to the community. This phenomenon has been dubbed by Native American communities as the “helicopter” phenomenon, in which researchers fly in, land only long enough to reap data, and leave immediately afterwards, providing no benefit to the community.[158]

One frequently mentioned strategy for giving back to the community is the presentation, publication, and distribution of reports and newsletters which provide feedback regarding the study’s progress, findings, and implications.[44, 115, 148] This feedback should also acknowledge the value of the community’s participation in the study.[95] Marmor and her associates[92] found this ongoing communication was much more important to participants than incentives such as coffee mugs, pens, and key chains. Some researchers (including the Jackson Heart Study) also include health promotion and resource information into these feedback materials.[41, 44, 154] Failure to provide feedback can be viewed as a breach of the relationship of the researcher and community.[69]

Providing employment opportunities for persons within the community is another strategy for giving back.[125] Church and community members can be employed as outreach workers, and clerical support staff, among other vital roles.[95] In addition to hiring all study staff and administrators from the African American community, the National Heart, Lung and Blood Institute (NHLBI), hired an African American community physician to serve as the director and chief medical officer for the NHLBI field site established for the Jackson Heart Study in Jackson. She is very active in community partnership activities across the tri-county Jackson Heart Study area.

<u>Social Context.</u> The dissemination of findings that do not take social context into account can be damaging and demoralizing to minority communities.[150] The discovery and reporting of high rates of negative health findings should be accompanied by plausible solutions which can lower risks and improve health outcomes.[95, 125] African American participation in health research is particularly salient given the significant and well-documented disparities in almost every major health condition. As addressed earlier, the Tuskegee study provides a symbol for the distrust of research among African Americans, and may or may not serve as a significant deterrent to research participation. In addition to the historical context of research mistreatment, racism and discrimination, social and communal values of family and religion were often operative factors influencing trust and research participation.

Understanding realities of the community within which research is to be conducted can go a long way in addressing the issues of trust shaped by longstanding social, economic, and political history. Gauthier and Clarke[119] suggested taking walking tours of the area with community members to learn the community’s history. From such endeavors, Gallagher-Thompson and others[118] reported explicit recruitment strategies reflective of the social context of study participants. Latino family caregivers were successfully recruited using value laden approaches of *familismo* (family values), *personolismo* (proper interpersonal relationships and social interactions), *presentismo* (short term goal orientation), and *jerarquismo* (hierarchical social order).

Sullivan and her associates[98] interviewed 41 community-based research advisors to determine their experiences and perceptions regarding the relationship of researchers to the community in community-based research. These participants believed that much of the community-based research focused on stereotypes and health problems that stigmatized ethnoracial minority communities. The findings of the research focused strongly on outcomes of social disadvantage rather than root causes. Most research also lacked community benefit, cultural appropriateness, feedback, or means of sustainability of effective procedures.

King[159] asserts that research which explores biological determinants of disease among racial groups should be preceded by research that explores the social, cultural, and environmental determinants of disease. It is only by exploring these determinants that researchers can use adequate statistical controls to reliably establish causal mechanisms. Input from the community regarding the social meaning of disease can also assist in identifying appropriate, effective, and acceptable interventions to address health problems in minority populations.[150]

Ethnicity is often considered by researchers and others as a proxy for poverty, thus denying the significant heterogeneity in social context for a particular community. When translating research into practice, it is essential that researchers recognize that there is considerable heterogeneity within and among ethnoracial groups.[133, 150] The definition of community must take into account commonalities based on geography, shared interest, social and political history, and ethnic identification as well as variations imposed by religious affiliation, socioeconomic status, generational status, acculturation, language skills, and immigration history.[133, 150, 160]

Implications and Recommendations for National Children's Study

Potential recommendations aimed at engendering communal trust by involving communities as co-investigators for consideration in the National Children's Study could include:

- Engaging HBCUs and other key ethnic organizations as key elements of the study in relevant National Children's Study sites.
- Engaging key community stakeholders, developing a community advisory board, and implementing the recommendations of the National Children's Study White papers on *Developing a Community Involvement* Strategy[153] and *Assessment of Existing Linkages with Local Communities among Potential Research Sites for the National Children's Study.*[152]
- Generally educating the community broadly regarding research:

    - Conducting community forums to discuss and improve understanding of genetic and environmental research.
- Providing information about the National Children's Study specifically across the community by implementing the recommendations of the report of the Ogilvy group: *Approaches to National Children's Study Message Development for Health Care Providers and Community Organization Representatives.*[161]
- Using a wide variety of media and person-to-person contact to disseminate information and raise awareness of the National Children's Study.
- Involving persons from the community in the interviewer selection and training process to assure that nuances of culturally appropriate communication and discernment practices are interwoven throughout staff and investigator training processes:
    - Community co-involvement in developing criteria and job descriptions through membership in a Study Selection and Training Committee.
    - Recruiting staff and investigators from the African American community to assure that the study is "of the community" and a context in which participants might feel more secure about asking questions and raising concerns about the study.
- Negotiating with businesses to support the study by providing paid time off for participants to attend study visits and schools to allow children to miss without penalty.
- Developing an Oversight and Evaluation Committee made up of community members to meet bi-annually and go over the evaluations from study participants and suggest ways to improve or change interactions and conduct of the study.
- Including the community in study decision making at all levels:
    - Developing formal mechanisms for community members to collaborate in the development of study protocols.
    - Configuring local site and study-wide Steering Committees to include voting community members.
    - Including community members on all major study committees.
    - Assuring community involvement in decisions regarding use of sensitive samples or study materials, especially genetic material.
    - Including community members as co-authors on research papers reporting study findings.

    - Co-writing study manuals of operations and training manuals with community members.
- Giving back to the community at multiple levels:
    - Could a National Children's Study "Healthy Children, Healthy Communities" Scholarship Fund be established and a donation made for every visit of every participant? Could National Children's Study sites develop a cadre of local supporters who would contribute a small sum to recognize the importance of having this study in their midst? A National Children's Study Council of Peers could review applications for community scholarships (perhaps $1000 limit) for African American students. The scholarships could be awarded for pursuit of public health and research curricula to provide capacity building for increasing the pool of minority researchers.
    - Hosting parades or family-oriented events (perhaps on or around Juneteenth or some similar minority oriented occasion) as an occasion for persons in the cohort to share first hand experiences with research and for the community to hear regular updates on study findings as they emerge. The first such gathering should be the kick-off of the study in each community
    - Developing a virtual resource directory with support of a local foundation or other community venue to provide up-to-date information to the cohort and the community on accessing a wide variety of health, economic, and social resources, services, and programs
    - Connecting with other community groups, such as the police, neighborhood watch programs, scouts, and others, to promote and support issues of concern to the entire community—for example, National Children's Study speaks WITH the police on violence.
    - Providing or participating in free community health screenings.
    - Providing ongoing health education activities with the community.
    - Offering a Speaker's Bureau of National Children's Study investigators and staff.

IV. SUMMARY AND RECOMMENDATIONS

Issues of trust proceed from a history of past and current abuses, and they have both frank and subtle impact on research participation among African Americans today. Tuskegee serves as a metaphor for this background issue, but does not prevent effective recruitment of African American research participation. When issues of trust are paramount in recruitment and retention efforts, African Americans do take part in research. Recruitment tends to be more successful when population heterogeneity is recognized and multiple strategies are employed. Nontraditional perspectives are needed that consider the sociocultural context of mistrust—historical and contemporary, as well as the familial and religious factors that are important to many African Americans. Implementing effective strategies depends upon researchers confronting the social, historical, and cultural factors associated with racism, and exercising social responsibility in recruiting and retaining African American research participation in particular settings. That entails moving beyond a singular commitment to generating scientific knowledge. Commitment is needed to join hands with local communities in order to discern the best practices for engaging research participation for all cultures, particularly those most often underrepresented—African Americans and other minorities. The National Children's Study faces a monumental challenge in recruiting among the most vulnerable of participants—children from preconception to birth and their mothers. Inherent in this challenge is a singular and unique opportunity to contribute to developing a science of recruiting research participation for women and children of color across the nation. To what extent, and by what methods, is this study able to penetrate the "complex web of issues" where deep-seated and well-founded fears and apprehensions of research lie alongside optimism, hope, and a desire to contribute to the greater good, and obtain African American research participation? To this end, we recommend that the National Children's Study incorporate an embedded longitudinal study of research participation that:

- Selects communities with disparate demographic, geographic, and sociopolitical contexts in which to compare community-specific recruitment and retention processes and outcomes.
- Specifies a conceptual approach to recruitment and retention (e.g., social marketing, community-driven, participatory).
- Incorporates multi-method approaches to chart research attitudes and beliefs, measures of trust, impact of POPCI factors, and experiences and meaning of

research participation or nonparticipation, among those invited to participate and key community informants.

- Incorporates similar multi-method approaches to chart analogous factors among the research team and lead investigators.
- Addresses ethical and cultural dimensions of research participation among all key partners.
- Details trust-building and damaging factors and strategies across the duration of the study.

In addition, specific strategies of recruitment and retention are recommended to inform building interpersonal and institutional trust among individual participants and their communities. Though this *White Paper* focused recruitment and retention issues for African Americans, similar ethnic and culture-based fears and apprehensions reside in other communities of color. Similar strategies of community engagement and cultural sensitivity should be employed within each ethnic subgroup to be included in the National Children's Study. Table 7 summarizes key recommendations in each category of the POPCI model in accordance with the level of trust sought. These recommended strategies were synthesized by carefully examining the ways in which trust acts through the factors that shape and direct individual, organizational, protocol, and community involvement for research participation. Information from the literature, and its social, cultural, and individual implications, can provide a conceptual roadmap of strategies for consideration in the National Children's Study to recruit a representative sample of African American and other minority research participation. This information may be used to promote well-founded trust and to recruit well-informed representative samples of African American and other minority women and children who will become well-served participants in the National Children's Study.

Table 7. Recommended Strategies for Recruitment and Retention Strategies that Address Issues of Trust Regarding Research Participation in African American Women and Children for the National Children's Study

POPCI Variable	Category	Interpersonal Trust	Institutional Trust
Participant	**Demographics / Networks**	• Provide opportunities for inclusion of family, churches, and social networks in research decision making • Invite and acknowledge contributions as participants, not subjects • Tailor strategies to address known barriers	• Knowledge of community demographics and networks • Speak with groups of individuals and their families / churches or other significant organizations
	Health Status / Risk Factors	• Communication of personal health benefits	• Community-wide educational "how to" forums on child health, parenting, and other study-relevant topics
	Health Beliefs, Attitudes, & Experiences	• Respect for cultural beliefs • Seek out and obtain support of individual health care providers to build on trusting relationships • Communicate long term promise of the study	• Clarify role of community providers • Develop referral mechanisms • Create opportunities for community storytelling around health issues to engage experiences
	Research Beliefs, Attitudes, & Experiences	• Communication of benefits to family, ethnic group, and community at large • Communication of disadvantages and dangers of participation	• Community forums to discuss research study "in their midst," its meaning for community and residents, and engage experiences
Organization	**Compatibility**	• Ethnic match of research team; include female and African American lead investigators in communities with high % African American • Select staff for interpersonal skills and study commitment	• "Do time" in community • Social responsibility of investigators made explicit • Confront organizational culture, racist practices, and reputation in the community • Study organization to provide culturally sensitive technical and instrumental assistance to community
	Climate	• Train staff to attend to issues of "double consciousness" • Attend to building organizational climate for collaboration and growth	• Funder commitment to provide sufficient $ for fiscal, human, and material resources • Study organization hires from the community and commits to capacity building among employees • HBCUs and other community organizations as funded sites • Address interdisciplinary and cultural differences

Table 7. Recommended Strategies for Recruitment and Retention Strategies that Address Issues of Trust Regarding Research Participation in African American Women and Children for the National Children's Study			
POPCI Variable	**Category**	**Interpersonal Trust**	**Institutional Trust**
	Continuity	• Provide personalized attention with easy contact • Same interviewers/staff contacting participants for data collection • Communicate appreciation of staff and participants	• Highlight continuous nature of study with varied public communications, especially participant-friendly web site • Ongoing evaluation of satisfaction with study-participants, community, and investigators
	Accessibility	• Central community location • Well maintained facility	• Study sites as "home" for participants
Protocol	**Research Design**	• Well articulated, theoretically based plan for recruitment and retention in each site • Use multiple methods of recruiting with careful participant tracking for retention • Inclusive sample design with multifaceted approaches • Culturally sensitive data collection methods / instruments	• Collaborative study planning with community
	Consent	• Assurances regarding use and control of data, particularly DNA and biological specimens • Emphasize confidentiality • Obtain Certificate of Confidentiality • Emphasize voluntary involvement and implement explicit process consent • Well communicated incentives • Culturally appropriate language and reading level • Multiple methods of consent information	• Community involvement in writing consent forms • Community education on "process" consent • Data sharing agreements in place • Mechanisms for screening collaborating researchers with community involvement • Ongoing forums regarding research ethics and use of data, especially genetic materials
	Accommodation	• Use of reminders, in-person visits • Limit time required for data collection • Flexible scheduling and site of data collection • Address unique barriers of participants	• Ongoing satisfaction studies to evaluate study ability to accommodate participant needs • Engage community board to devise creative responses to ongoing findings
	Quality Assurance	• Rapid feedback on exam results and questions • Regular newsletter • Tracking mechanisms to provide rapid and frequent feedback to staff on recruitment and data quality	• Make study oversight mechanisms known and transparent to participants • Develop community oversight mechanisms, e.g., Community Monitoring Board

Table 7. Recommended Strategies for Recruitment and Retention Strategies that Address Issues of Trust Regarding Research Participation in African American Women and Children for the National Children's Study			
POPCI Variable	**Category**	**Interpersonal Trust**	**Institutional Trust**
Community Involvement	**Mobilization**	• Media and person-to-person contact to raise awareness • Gain support of key organizations—churches, business, civic, political • Identify community spokespersons • Rely on existing networks • Community Advisory Board	• Engage social marketing expertise for study message design • Community forums to increase knowledge and awareness of research
	Partnership	• Community and researchers raise research questions, design protocols, and recruit participation • Community Partnership Board	• Mutual direction and monitoring of study • Participatory action models evident
	Translation	• Giving back to the community and participants at every opportunity	• Community forums for discussion of study and findings
	Social Context	• Get to know history and perspectives of community • Respect culture and ecology of community in study design and recruitment	• Confront culture, racism, and reputation of community and research organization

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