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The Significance of Trust in the Research Consent Process With African Americans¹

Catherine E. Earl

Pamela J. Penney

Nurses and other health scientists face serious challenges in recruiting African Americans as research participants. The trend in published research shows a declining representation of African Americans in study groups, particularly in nursing and clinical trial research (Mouton, Harris, Rovi, Solorzano, & Johnson, 1997; Shavers-Hornaday, Lynch, Burmeister, & Torner, 1997; Plowden & Wenger, 2001). Published research involving African Americans has almost disappeared from the literature in major American Psychological Association journals since the 1970s; the overall percentage of research studies involving African Americans is a mere 3.6% (Graham, 1992).

A review of the literature offers reasons for African American's lack of participation in studies. Issues include the participants' lack of understanding and lack of trust of the informed consent process and of researchers because they have little confidence in the researchers' honesty or reliability. The informed consent process involves informing participants of risks and benefits and facilitating intentions to participate in studies. The lack of explanation of the informed consent with African American study participants has profoundly influenced their unwillingness to participate in research studies. African Americans have consistently expressed concerns about researchers who make statements to persuade them to participate in research then fail to keep their word about how the study was conducted resulting in a lack of trust (Corbie-Smith, Thomas, Williams, & Moody-Ayers, 1999). The purpose of this article is to discuss the historical events influencing the lack of trust of African Americans as participants in research

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studies, the lack of understanding and trust of the informed consent process, the application of essential conditions that must be fulfilled in the informed consent process, a set of concepts to stimulate an increased understanding of how to gain trust with African Americans, and recommendations to improve recruitment of African Americans as research participants.

Historical Events Shaping Lack of Trust Among African Americans as Participants in Research Studies

Several historical events have shaped the development of African American attitudes toward participation in research studies. Critical influences including social, historical, political, and economic movements have had a great effect on African Americans. These events have affected their behavior, often resulting in the sense that they have a powerless status.

Slavery and Powerlessness

Lack of trust with the informed consent process today derives from a long history of exploitation dating back to slavery. When slavery was introduced in the eighteenth century, African Americans were bought and sold as pieces of property for cheap labor. The use of slaves as subjects for dissection and medical experiments took place. In addition, slaves were denied the legal right to refuse to participate in research studies (Mays, 1986).

Gamble (1997) presented two research studies that showed examples of the abuse slaves underwent as research participants. The first was a series of brutal experiments to test remedies for heatstroke. Slaves were placed in a heat-intensive pit and given various medications to evaluate which ones worked best for tolerating the heat. The purpose of the research was to be able to force slaves to work longer hours in extreme temperatures. In the second experiment, three slaves underwent more than 30 painful operations without anesthesia to evaluate ways to repair vesicovaginal fistulas.

The Tuskegee Syphilis Experiment

As described by Green, Maisiak, Wang, Britt, and Ebeling (1997), the story of the Tuskegee Syphilis Experiment, conducted from 1932 to 1972 in Alabama, continues to haunt the African American community. The study involved 400 African Americans infected with syphilis. The experiment was designed to examine development of the disease, not to provide proper treatment, yet these men were under the impression that they were being treated

for syphilis. This was allowed to happen despite the discovery of new drugs to treat syphilis.

Edmonston-Zagreb Vaccine

Gamble (1997) reported that research studies continue to confirm the fears and threats of African Americans toward the informed consent process as demonstrated by the 1991 experimental Edmonston-Zagreb vaccine. Nine hundred African American and Latino infants received the vaccine; however, the parents were not informed that the vaccine was not licensed in the United States nor were they informed that the vaccine had increased death rates in Africa.

Lack of Understanding and Trust of the Informed Consent Process

El-Sadr and Capps (1992) suggested that the lack of knowledge about the nature, purpose, and procedures of medical research is a major barrier to recruitment of African Americans as research participants. Roberson (1994) found that terms used in research studies are foreign to minority participants. An evaluation of African American views on research indicate that they have difficulty understanding informed consent forms (Freimuth et al., 2001). In a research study conducted by Corbie-Smith et al. (1999), few of the African American participants understood research protocols. When the participants described the difficulties of giving informed consent, they expressed a lack of knowledge about technical and medical vocabulary.

A Set of Concepts to Stimulate Increased Understanding of the Informed Consent Process

The publication of the Belmont report by the National Commission for Protection of Human Subjects of Behavioral Based Research in 1979 explains the ethical principles underlying the informed consent process today (Department of Health and Human Services, 1979). The main purpose of this report was to protect minority populations such as African Americans from potential abuse. Alt-White (1995) has further applied these principles in her discussion of three essential conditions that must be fulfilled with the informed consent process among the elderly; these conditions have application to conducting research with African Americans. The first essential condition, "freedom to decide," stipulates the need to have a sense of freedom to

make informed decisions about participation. African Americans have been forced to participate in studies, often enduring harsh and unethical treatment. For example, in the Tuskegee Syphilis Experiment, poor male sharecroppers with syphilis were not told they had the disease, nor were they treated, but physicians told them they were being treated for “bad blood” when they were performing lumbar punctures. The men were informed that lumbar punctures were therapeutic, not diagnostic (Gamble, 1997). “Information clarity,” the second essential condition, requires any potential participant to have information that is clear, understandable, and usable in order to make an informed decision. This condition relates to the difficulties with medical terminology and vocabulary often used in consent forms, which African Americans have noted as complex and confusing. The third essential condition, “decision-making capacity,” refers to potential participants having the capacity to make decisions for themselves and can be applied to improving trust with African Americans as research participants. Attentiveness to explaining the risks, benefits, and alternative treatments during the informed consent process helps the participant to make an informed decision.

A further way to operationalize the conditions presented by Alt-White (1995) would be to use the six concepts developed by Dennis and Neese (2000) as part of their research with African Americans. These concepts are historical cognizance, sanctioning, trust building, recognition of group heterogeneity, mutuality, and researcher self-reflection and introspection. Further discussion in this article will focus on the integration and application of Alt-White’s conditions and the concepts of Dennis and Neese to stimulate an increased understanding of the informed consent process and to assist researchers to establish trust with African Americans as research participants.

Historical Cognizance

Historical events have contributed to the negative opinions African Americans have about participating in research. Many older African Americans may have been research participants themselves or may have family or relatives who were abused as study participants; consequently, suspicion and apprehension were created. These attitudes have posed a barrier to African Americans’ interest in being involved in research. Historically, the lack of understanding of research terminology and informed consent has served as an obstruction to participation in research studies. These lingering effects of negative experiences have created doubt about the intent of research. “Insidious skepticism about the meaning and goodness of research” remains

a barrier to participation for African Americans as research participants (Dennis, 1999, p. 281).

Sanctioning

Sanctioning involves developing relationships with the community in which one is conducting the research (Dennis & Neese, 2000). According to Leininger, (1991, 1990), when a researcher is new to the community, the participants will initially only give pieces of information to the researcher. Researchers gain trust as they continue to become active members of the community. In most communities, there is reluctance to share cultural secrets and vital information is often withheld. Plowden and Wenger (2001) explained that generally a gatekeeper controls entry into the culture. According to Dennis and Neese (2000), becoming familiar with the socioeconomic and political context of potential participants must precede the implementation of the research study. Understanding the community and developing alliances with key leaders build a cooperative and collaborative environment.

Trust Building

Trust is a firm belief in the honesty and reliability of the researcher. Positive attitudes and actions of researchers can help shape and fuel community trust. To begin to build trust, an appreciation of the specific needs of African Americans as research participants must be understood. Furthermore, trust building among African Americans requires a significant investment of time in the community. Laverentz, Cox, and Jordan (1999) found that cultural issues and barriers can be overcome when there is a willingness to take time to gain trust and respect. Corbie-Smith et al. (1999) found that African American responses to a question about what comes to mind with the term *medical research* included the following: being lied to, corruption, deception, negligence, using people, sacrifice, cruelty, and guinea pig. Researchers who are aware of these ethical concerns will be able to address these issues throughout the research study, which will continue their efforts toward building trust.

Mutuality

Trust and mutuality are "hierarchical, inextricably interwoven concepts" (Dennis & Neese, 2000, p. 9). Building a trusting relationship forms the foundation of a mutually beneficial relationship. The need to maintain honest communication and to ensure access to complete information is central to

a mutually beneficial relationship (Dennis & Neese, 2000). African Americans perceive research to be of greater importance to the researcher than to them. There is an overall perception that African Americans and their communities have been used to collect data without gaining any benefits from the results of studies (Wenger & Plowden, 2000).

Recognition of Heterogeneity

African Americans, similar to other minority groups, are a heterogeneous group. Knowing how an individual's history has affected attitudes toward research is an important aspect of respecting differences within groups. Differences in lifestyles exist in the African American communities. Depending on one's background, literacy differences may exist that may affect understanding of the informed consent document. Education, religion, socioeconomic factors, geographic location, gender, and age may affect attitudes toward research. Generation factors may affect participation in studies because the elderly may place their past negative experiences at the forefront when making a decision to be involved in a study.

Researcher Self-Reflection and Introspection

If the researcher does not have a sincere motivation to improve the health and well-being of African Americans, lack of trust in health care professionals will remain a barrier to participation. The researcher must ensure that the protection of human subjects is applied consistently throughout the research study.

RECOMMENDATIONS

The integration of three essential conditions (Alt-White, 1995) and six concepts (Dennis & Neese, 2000) offers a foundation for a set of recommendations to strengthen the approach to the informed consent process with African Americans.

Three strategic categories are proposed to serve as recommendations for stimulating trust and improving the informed consent process. These categories are: approaching issues in research with African Americans (historical events, community, diversity, and self-introspection), developing informed consent materials for African Americans as research participants, and explaining informed consent to African Americans as research participants.

*Approaching Issues in Research With
African Americans as Research Participants*

Because historical events serve as a barrier to participation in studies, nurse researchers must develop a comprehensive understanding of the past issues that contribute to African Americans' complex attitudes toward research. The concerns and fears of African Americans have a legitimate basis in historical reality. To build trust, acknowledge the existence of past problems and be willing to have frank discussions using honest and open communication. Use aspects of "freedom to decide" and "decision-making capacity" conditions (Alt-White, 1995) to guide these discussions.

Understanding history helps to attain sanctioning. Sanctioning can be achieved by obtaining community support for developing the informed consent documents. This approach also helps the researcher work with participants to begin to establish trusting relationships. Use examples and explanations of past research to make it clear how results contribute to the welfare of the community. Ask the community to help identify recruitment strategies, including introducing the informed consent process to the participants themselves.

Diversity in the population must be recognized. Life experiences and shifting populations create an increased diversity within groups. To recognize diversity, assess factors such as generation issues, education, religious affiliation, social and economic status, geographic location, values, and gender. These factors require new ways to implement the informed consent process, which are discussed later in this article.

To be involved in research with African Americans, the nurse researcher must have a sincere interest in contributing to the general health and well-being of the African American community. Caring about the community means creating an environment where trust is essential if active participation is expected. Listening conveys respect, which is the basis of trust and is essential for active participation by African Americans as research participants.

Developing Informed Consent Material for African Americans

When developing the informed consent forms, apply the second essential condition, information clarity (Alt-White, 1995). Nurse researchers should engage community stakeholders, including local representatives from churches and schools, to assist in examining how to write an understandable, readable informed consent form. Literacy issues should be addressed through the assistance of community educators. Nurse researchers should

maintain a broad visibility in the community through working closely with the media, including newspapers and magazines that African Americans read and trust to be credible. Nurse researchers should partner with community members to assist in publishing explanations of informed consent and other aspects of research.

*Explaining Informed Consent to
African Americans as Research Participants*

Based on Alt-White's (1995) conditions to elicit freedom to decide and informed decision-making, discuss in detail any benefits and risks of the study, including alternative treatments. To help African Americans evaluate whether they want to participate, encourage them to weigh these factors as they relate to their own situations. The use of open-ended questions and the assistance of community members will help them think through how participation is of benefit to them and their community.

During the explanation of the informed consent process, the mutual gain from participation in the study should be emphasized. African Americans need assurance that they will have access to the research findings and that the welfare of the community is of mutual interest to all involved in the research study. Maintain honesty and communicate clearly when reviewing the informed consent process; this provides a strong foundation for the development of trust. Participants should be given copies of informed consent documents. Researchers should stress that any questions are welcome and offer the names and telephone numbers of researchers for any further clarification. This reaffirms what was agreed to in the informed consent document and confirms the researchers' desire to ensure a clear understanding of the information.

CONCLUSION

A true health crisis exists for African Americans. Nurse scientists must first understand the historical context of this population and how this history creates difficulty in meeting the conditions for giving informed consent for research participation. To have an impact on the current health disparity, recruitment of African Americans as participants is desperately needed. The integration of the three conditions (Alt-White, 1995) underlying informed consent with concepts to operationalize them with African Americans have been used to develop strategies to improve the process of obtaining informed

consent with this population. Consideration and use of these strategies by nurse scientists will help address African Americans' concerns and assist in creating understanding and comfort for their participation in research.

NOTE

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REFERENCES

- Alt-White, A. C. (1995). Obtaining informed consent from the elderly. *Western Journal of Nursing Research*, 17(6), 700-705.
- Corbie-Smith, G., Thomas, S. B., Williams, M. V., & Moody-Ayers. (1999). Attitudes and beliefs of African Americans toward participation in medical research. *Journal of General Internal Medicine*, 14, 537-546.
- Dennis, B. P. (1999). The origin and nature of informed consent: Experiences among vulnerable groups. *Journal of Professional Nursing*, 15, 281-287.
- Dennis, B. P., & Neese, J. B. (2000). Recruitment and retention of African American elders into community-based research: Lessons learned. *Archives of Psychiatric Nursing*, 14(1), 3-11.
- El-Sadr, W., & Capps, L. (1992). The challenge of minority recruitment in clinical trials for AIDS. *Journal of the American Medical Association*, 267, 954-7.
- Freimuth, V. S., Quinn, S. C., Thomas, S. B., Cole, G., Zook, E., & Duncan, T. (2001). African Americans' views on research and the Tuskegee syphilis study. *Social Science and Medicine*, 52, 797-808.
- Gamble, V. N. (1997). Under the shadow of Tuskegee: African Americans and health care. *American Journal of Public Health*, 87, 1773-1778.
- Graham, S. (1992). Most of the subjects were White and middle class. *American Psychologist*, 47(5), 629-639.
- Green, B. L., Maisiak, R., Wang, M. Q., Britt, M. F., & Ebeling, N. (1997). Participation in health education health promotion and health research by Americans: Effects of the Tuskegee syphilis experiment. *Journal of Health Education*, 28(4), 196.
- Laverentz, M. L., Cox, C. C., & Jordan, M. (1999). The Nuer nutrition and education program: Breaking down cultural barriers. *Health Care Women International*, 20(6), 593-601.
- Leininger, M. M. (1990). Ethnomethods: The philosophic and epistemic bases to explicate transcultural nursing knowledge. *Journal of Transcultural Nursing*, 1(2), 40-51.
- Leininger, M. M. (1991). Becoming aware of types of health practitioners and cultural impositions. *Journal of Transcultural Nursing*, 2(2), 32-39.
- Mays, V. M. (1986). Identity development of Black Americans: The role of history and the importance of ethnicity. *American Journal of Psychotherapy*, 40(4), 582-593.
- Mouton, C. P., Harris, S., Rovi, S., Solorzano, P., & Johnson, M. (1997). Barriers to Black women's participation in cancer clinical trials. *Journal of the National Medical Association*, 89(11), 721-727.

- Plowden, K. O., & Wenger, A. F. (2001). Stranger to friend enabler: Creating a community of caring in African American research using ethnonursing methods. *Journal of Transcultural Nursing, 12*(1), 34-39.
- Roberson, N. (1994). Clinical trial participation: Viewpoints from racial/ethnic groups. *Cancer Supplement, 74*, 2687-2691.
- Shavers-Hornaday, V. L., Lynch, C. F., Burmeister, L. F., & Torner, J. C. (1997). Why are African Americans underrepresented in medical research studies? Impediments to participation. *Ethnicity and Health, 2*(1/2), 31-45.
- Wenger, A.F.Z., & Plowden, K. O. (2000). The meaning of faith and health as perceived by African Americans faith communities in an urban setting. Manuscript preparation, Emory University.