

### NIH Public Access

**Author Manuscript** 

Int J Dermatol. Author manuscript; available in PMC 2013 May 06.

#### Published in final edited form as:

Int J Dermatol. 2011 April; 50(4): 385–395. doi:10.1111/j.1365-4632.2010.04813.x.

## Recruiting underserved populations to dermatologic research: a systematic review

Chaya R. Spears, BS, MA<sup>1</sup>, Bridgit V. Nolan, MD<sup>2</sup>, Jenna L. O'Neill, MD<sup>2</sup>, Thomas A. Arcury, PhD<sup>1</sup>, Joseph G. Grzywacz, PhD<sup>1</sup>, and Steven R. Feldman, MD, PhD<sup>2,3,4</sup>

<sup>1</sup>Department of Family Medicine, Wake Forest University School of Medicine, Winston-Salem, NC, USA

<sup>2</sup>Department of Dermatology, Wake Forest University School of Medicine, Winston-Salem, NC, USA

<sup>3</sup>Department of Pathology, Wake Forest University School of Medicine, Winston-Salem, NC, USA

<sup>4</sup>Department of Public Health Sciences, Wake Forest University School of Medicine, Winston-Salem, NC, USA

#### Abstract

Recruitment of participants to dermatologic research studies can be challenging, particularly with historically underserved populations. Recruitment of these groups is essential to ethical, valid, and useful dermatologic research. This article discusses findings from a review of 78 studies that examined factors influencing participation in health research studies with an emphasis on underserved populations, particularly women and ethnic minorities. The most commonly encountered barriers to research participation are mistrust of research, lack of access to research programs, and culturally incompetent research design. Motives to participate in research include receipt of benefit from participation, perceived opportunities to help others, and culturally competent research design, community-based recruitment, and easily understandable informed consent. These factors should be considered when recruiting subjects for dermatologic research, especially when recruitment of underserved populations is desired. In addition, the literature demonstrates a paucity of research among rural residents, infants, and children, as well as within clinical dermatologic research.

#### Introduction

Recruiting participants to medical research is challenging, particularly from historically underserved populations, such as women, ethnic minorities, elders, and rural residents.<sup>1,2</sup> Appropriate sampling and representation is essential to conducting ethical research, obtaining valid results, and forming clinically relevant and broadly applicable conclusions. In some chronic disease states, such as atopic dermatitis, individuals most likely to be affected are the least likely to participate in health research.<sup>2,3</sup> Atopic dermatitis is more prevalent among rural and minority groups, two underrepresented populations in medical research.<sup>1,4</sup> Additionally, some dermatologic conditions are over-represented in certain ethnic or demographic groups, further emphasizing the need for representation of these

<sup>© 2011</sup> The International Society of Dermatology

Correspondence: Steven R. Feldman, MD, PhD, Department of Dermatology, Wake Forest University School of Medicine, Medical Center Boulevard, Winston-Salem, NC 27157 1071, USA, sfeldman@wfubmc.edu. Conflicts of interest: None.

groups in clinical trials and other research endeavors. However, the problems of recruitment of traditionally underserved populations are not unique to dermatologic research and suggest that some studies of health disparities may suffer from selection bias. Similarly, though some dermatologic data can be obtained retrospectively, for example, through medical records and clinic sites, such data also suffer from selection bias, as people who have access to such services and institutions may differ from those who do not. Consequently, problems of recruitment are important for dermatologic researchers who cannot adequately address research questions through examination of retrospective and potentially biased data sets.

Issues surrounding the difficulty of recruiting under-served populations to dermatologic research have not been explored. However, other areas of medical research, including cancer,<sup>5–7</sup> cardiovascular disease,<sup>8</sup> and stroke prevention research<sup>9</sup> have identified areas of difficulty and various reasons for poor recruitment of underserved populations, including: logistical barriers or practical difficulties, such as child care, transportation, or competing demands of daily life;<sup>10,11</sup> lack of information due to limited awareness of the availability or importance of medical research,<sup>12</sup> beliefs about randomization<sup>10</sup> or informed consent;<sup>3</sup> sociocultural factors, such as the influence of family members' and friends' apprehension about participation in research or fatalistic religious beliefs about disease;<sup>13,14</sup> and specific attitudes, such as negative feelings toward research,<sup>15</sup> distrust of the medical system,<sup>16</sup> fear of discrimination,<sup>3</sup> or negative personal experiences with the healthcare system.<sup>17</sup>

Related to the difficulty of recruiting underserved populations to research are the unique ethical issues surrounding genetic research.<sup>18–22</sup> Many chronic dermatologic conditions, such as atopic dermatitis, result from complex interactions between genetics and environment. Potential research participants may be concerned that their genetic information may be used against them by insurance companies or future employers.<sup>23</sup> Participants may fear that demonstration of genetic variation among subsets of the population may increase social discrimination against those groups.<sup>23</sup> Additionally, individuals may not want to deal with the emotional distress of knowing they carry genes that may confer the risk of disease.<sup>9</sup>

Furthermore, the hygiene hypothesis suggests that early exposure to environmental pathogens has an inverse relationship to the development of atopic dermatitis, other allergic disorders, and various common dermatologic diseases.<sup>24</sup> In addition, several candidate gene loci have been identified in the pathogenesis of atopic dermatitis.<sup>25</sup> Research to further explore the gene–environment interaction in the development of atopic diseases will require recruitment of minority groups living in rural communities and participants willing to take part in genetic research studies. Collection of genetic samples from children is particularly challenging, especially among groups who have not traditionally been research participants. Identification of barriers to research participation and factors associated with successful recruitment of underserved populations to other types of medical research will facilitate effective recruitment of these groups to dermatologic studies.

In this paper, we review the literature on recruitment of underserved populations to biomedical research with emphasis on barriers and inducements to participation and suggested solutions. We address two questions. First, what factors may influence participation of underserved populations in medical research? Second, what methods have been identified to increase research participation by members of these populations?

#### Methods

We conducted a search of PUBMED, Google Scholar, and Web of Science for all relevant articles from 1990 through 2009 using the following search terms: participation in health research, participation in medical research, underserved populations, women, and racial and

ethnic minorities. Studies were included in our analysis if they presented: systematic assessments of barriers and motives to participation, clear description of methods employed, and reports of primary data. Each study was coded for: population studied, type of research conducted (i.e., qualitative or quantitative), barriers and inducements to participation, and suggested solutions for increasing research participation. Another member of the study team then reviewed the coded articles for consistency. Subgroup analysis of the various research types and specific underserved populations was also conducted.

Of the 151 articles initially reviewed, 78 met the inclusion criteria (Table 1). Of those, 19 used qualitative methods, 53 used quantitative methods, and six used both quantitative and qualitative methods. Qualitative analyses included thematic or conceptual analyses of nonnumeric data, such as discourse collected through focus groups and in-depth interviews. Quantitative analyses included statistical evaluations of numerical data collected through surveys, questionnaires, or secondary analysis of pre-existing numerical databases. Articles were organized into subgroups based on their primary focus on the following populations: (i) African-Americans, including subpopulations of men, elders, and women, n = 24 (31%); (ii) multiple ethnic groups, n = 10 (13%); (iii) women (without racial specification), n = 10(13%); (iv) general population (without racial or gender specification), n = 9 (12%); (v) research participants from other medical studies, n = 5 (6%); (vi) patients (including inpatients, outpatients, and ambulatory patients), n = 10 (13%); (vii) high-risk populations, based on demographics and behavior, n = 4 (5%); and (viii) healthcare providers and researchers, n = 6 (8%) (Table 1). Articles were also analyzed based on the type of medical research they examined, including: (i) clinical trials, n = 36 (46%); (ii) general medical research, n = 22 (28%); (iii) genetic research, n = 9 (12%); (iv) prevention research, n = 9(12%); and (v) epidemiology, n = 2 (3%).

#### Results

#### **Barriers to participation**

The most commonly reported barriers to individual participation included (Table 2): mistrust of research (32%) and lack of access to research due to geographic or other structural impediments (16.6%).<sup>27–29</sup> Culturally incompetent research designs that ignore culturespecific beliefs about illness, healthcare, and professionalism, the role of physicians, the nature of research and the testing it involves, and appropriate means of access to the target population were also prevalent barriers (15.3%).<sup>28,30</sup> Other commonly cited barriers included: lack of time (14.1%);<sup>31</sup> lack of information about research due to participants' or physicians' ignorance or misunderstandings (12.8%);<sup>32</sup> and mistrust of the medical community (12.8%).<sup>26</sup> Low socioeconomic status (12.8%) and associated deficiencies of insurance, access to healthcare, or literacy required for comprehension of study materials<sup>33</sup> also obstructed participation, as did the Guinea Pig Fear Factor (11.5%), that is, the fear of being objectified and used for experimentation rather than cared for and respected as an individual.<sup>34</sup> Fears of the nature or number of tests and procedures (8.9%),<sup>35</sup> side effects from test treatments (6.4%),<sup>36</sup> and the repercussions of genetic research (6.4%) – such as discrimination from peers and, especially, insurance providers or the creation of a genetically selective society 9,23,37 – were also found in the literature.

Three barriers to participation were unique to specific subsets of articles. For studies of multiple ethnic groups, knowledge of the Tuskegee Study of Untreated Syphilis proved inhibiting to individuals' participation due to worries that present day research may be similarly unethical or racially discriminating.<sup>38</sup> Studies of patients and high-risk populations demonstrated that fear of new medical knowledge could inhibit individual participation. For instance, some individuals hesitated to participate in HIV vaccine trials for fear that they would learn of their own seropositivity.<sup>39</sup> Finally, African-Americans and high-risk

populations were also inhibited by perceived social disapproval of participation. For some, objections raised by friends and loved ones were sufficient to halt their participation.<sup>13</sup>

No studies were identified that specifically addressed barriers to participation in dermatology-specific research. Hypothetical barriers might include: fear of embarrassment or stigmatization due to the presence of a skin condition on exposed areas (such as the hands or face); fear of side effects of study medications, which may be exacerbated by a lack of knowledge of dermatologic conditions and their treatments; or lack of access to research, as most dermatology research is conducted in specialty clinics or academic settings.

#### Motives for participation

The most commonly cited motives for an individual's participation included (Table 3): receipt of some benefit (20.5%) such as, monetary incentives, goods, services, or free medical care,<sup>40</sup> and the opportunity to help others (14.1%) by aiding in development of preventative measures or effective treatments for non-participants.<sup>16</sup> Culturally competent research design  $(8.9\%)^{41}$  and being at high risk for a disorder (7.6%) that might be better managed, treated, or cured through research<sup>42</sup> were common facilitators of participation. Similarly, trusting researchers (7.6%) to be benevolent, honest, and open encourages participation and is usually based on some previously established relationship between the researcher and the participants or their communities.<sup>43</sup> Relevance of the research topic (6.4%) due to its familiarity for potential participants or their personal or communal concerns about the issue motivates participation,<sup>44</sup> as do participant-centered study schedules and procedures (5.1%) that work around the time and transportation needs of participants.<sup>45</sup>

Several unique factors encouraged participation depending on the type of research and the subject populations. Patients and those at high risk for a disorder were motivated to participate due to possible disease prevention for themselves or society in general, but not necessarily an explicit concern for helping others.<sup>23</sup> Research participants and patients were more likely to participate if they had awareness of and access to research projects, meaning that they had knowledge of opportunities to participate in research and the means by which to do so.<sup>46</sup> Among healthcare providers and researchers, principal investigators' emphasis on minority recruitment or the relative importance and associated effort given to recruiting members of underserved populations.<sup>47</sup> Finally, for those at high risk for a disorder, the belief that participation entailed low risk of harm or injury encouraged participation.<sup>9,39</sup>

#### Solutions to improve participation

Many practical solutions to problems of recruitment of underserved populations have been proposed (Table 4). Some of these strategies focus on community-level action. For instance, community-based recruitment strategies (19.2%) build relationships with community leaders, key informants, and gatekeepers, can use former participant testimonials as sources of recruitment information, or may distribute study information through popular community sites such as churches and on buses.<sup>48</sup> Educational programs may seek to inform communities about projects (16.6%) and can include educational workshops or health fairs at which research projects are described and potential participants are screened or recruited.<sup>49</sup> Communities may also be engaged through incorporation of the target population at all levels of research design and implementation (6.4%) by including researchers who belong to the target population in project development and implementation or by forming an advisory committee comprised of members of the target population to inform and shape research goals and methods.<sup>15,50</sup>

Other strategies emphasize consideration of individual participants by making sure that informed consent is understandable (19.2%) or that materials are written in culturally appropriate and easily understood language, devoid of technical jargon, clearly delineating risks, benefits, and procedures involved.<sup>51</sup> Another suggested strategy includes attempting to increase participants' trust of researchers (19.2%) by establishing long-term relationships with participants and conveying a sense of caring for the health of individuals and their communities.<sup>43</sup> Provision of monetary and non-monetary benefits to participants (7.6%), including cash or cash equivalents, free study medication, compensation for parking or other expenses associated with study participation, or free medical or educational services and workshops<sup>26,52</sup> is another recommended solution. Similarly, overcoming socioeconomic barriers (6.4%) can also facilitate participation and may involve addressing participants' "real life issues," such as work schedules and familial responsibilities, lacking financial resources, or illiteracy that inhibits participation and comprehension of informed consent documents.<sup>27</sup>

Other suggested solutions focus on matters of study design and implementation, including designing research in a culturally competent fashion (20.5%) through use of ethnographic methods, which study human cultural behavior<sup>53</sup> and give attention to beliefs about disease, illness, and socially appropriate recruitment methods. <sup>14,41,54</sup> Ensuring that study schedules and procedures are participant-centered (14.1%) and are compatible with individuals' needs, values, beliefs, and resources, including scheduling study activities during non-work hours and providing home visits for disabled patients,<sup>28,45</sup> may also increase participation. Increasing physician engagement and participation in projects (7.6%) by encouraging otherwise uninvolved physicians to participate in the research process or making research projects geographically mobile so as to incorporate medical facilities and institutions that are unconnected to the institution or practice housing the program is also a recommended solution to problems of recruiting underserved populations.<sup>29,55</sup> Additionally, among highrisk populations, follow-up counseling might also defray concerns about new medical knowledge that results from research participation.<sup>9</sup>

#### Discussion

Recruiting historically underserved populations to medical research presents several challenges. Although there is a dearth of literature regarding this matter within the context of dermatologic research, difficulties found across a variety of medical interests are informative for designing dermatologic studies. Many salient barriers to participation in medical research are not specific to the topic or nature of the projects: mistrust of the medical community or research, lack of access and information about research projects, culturally incompetent research designs, and fear of being treated as an objectified subject with methods that may be painful and frightening transcend virtually every area of biomedical research. Some barriers to participation are of a practical nature, such as lack of time, transportation, information, and access. Others are more conceptual concerns; for instance, mistrust of research and the medical community, and cultural or religious beliefs. These conceptual barriers cannot be fully addressed or overcome with practical solutions, such as monetary incentives and provision of childcare. Other techniques are needed.

Mistrust, cultural conflict, and informed consent are related to one another. Many kinds of mistrust within different contexts are common outgrowths of cultural conflict and miscommunication. Just as different societies speak different languages, the language, perspectives, and logic of those working in medical research are not common to most members of society. In light of the Health Insurance Portability and Accountability Act (HIPAA) regulations, one may question the ability to make the consent process maximally understandable as well as HIPAA compliant. While the National Cancer Institute<sup>56</sup> suggests

composing informed consent documents at an eighth grade or lower level, this does not address the reality that, even within a given target population, individuals may have highly variable reading levels with some significantly lower than the eighth grade level. In such cases, researchers must tailor the informed consent process to meet individual needs and explain study materials in a clear and simple manner. In the absence of such individualistic customization of informed consent processes, persons already medically underserved may have difficulty comprehending the Institutional Review Board and HIPAA compliant consent processes, sense that medical research is not aligned or accommodating to their everyday lives, and mistrust the unfamiliar methods of medical research. Nonetheless, in order to garner participants from all sectors of the population, the "culture" of medical research and the jargon that we use needs to be translated into language that is common in the population with consideration of individual variations in literacy and language usage.<sup>57</sup>

Incomprehensible language and unfamiliar logic are barriers to trust and understanding. Trust is further undermined when the researcher asks for access to and use of intensely private and possibly life-threatening information or material. Engaging members of the groups we seek to recruit at all levels of the research endeavor may help researchers to develop projects that are practically amenable to the needs and constraints of the people we wish to enroll. Additionally, these advisors can serve as "cultural brokers," training the researchers as well as their fellow community members to speak a common language that is suited to and understood by both groups.<sup>58,59</sup> This, in turn, will make our research endeavors more transparent to those whose trust was reserved because our agendas were unknown.

Community-based participatory research emphasizes the importance of community participation in several aspects of research, including: (i) research question definition, data analysis and interpretation, and application of findings; (ii) education and direct correction of knowledge imbalances between researchers and participants and empowering participants to confront health problems; and (iii) social action.<sup>60</sup> Such a framework may lead to better understanding of the social context in which disease and treatment outcomes occur and may ultimately lead to better solutions.<sup>60</sup> Trust can be built by making research culturally compatible, incorporating members of the target population in all aspects of the research process, and by making study procedures and rationales apparent. Community-based participatory research facilitates trusting relationships and mutual understanding between researchers, participants, and their respective communities by placing emphasis on researchers' long-term commitments to communities and the return of study results to participants and their communities.<sup>57,60–62</sup> The evidence suggests that researchers who are in tune with participants' marital, religious, and community environment - all of which may influence an individual's decision to participate -are better able to recruit members of underserved communities. However, ethnographic research has also demonstrated that the community leaders, key informants, and gatekeepers who often serve as facilitators of recruitment are frequently non-representative of their communities.<sup>63–66</sup> As a result, researchers inadvertently alienate portions of the target population by including members of other segments of the group.<sup>64,65,67</sup> Purposeful recruitment from all segments of the target population can address sampling biases engendered by some community-based research strategies, less purposefully sampled studies of health disparities, and research utilizing retrospective data.<sup>64</sup> The literature discussed here suggests that as the trust of researchers and research processes increases, so will participation in research.

The Tuskegee Syphilis Study and many other instances of unethical research have added to potential participants' sense of distrust. When combined with the cultural conflict between researchers and underserved populations, recruitment suffers. Nonetheless, people often participate in research for their own personal benefit or through a desire to help others.

Addressing the barriers with practical, focused interventions may facilitate better recruitment.

#### Conclusions

Within medical research, lack of participation by under-served populations may result from practical or conceptual issues. Although barriers, inducements, and solutions to the problems of recruitment to participation are widely discussed in general medical research, little of this research is specific to dermatologic matters. In addition, of the systematic studies examined here, none focused on rural populations or recruitment of infants and young children. The elucidation of gene–environment interactions and their contributions to the pathogenesis and manifestation disease (e.g., atopic dermatitis) is often complicated by inability to recruit individuals most impacted by the disease (e.g., African-American and rural children). To answer questions regarding underserved populations, the barriers and motives to participation of these groups must be systematically identified so that they may be adequately addressed and overcome in future studies, especially among rural residents and their infants and young children.

#### Acknowledgments

This manuscript has been funded with the support of a NIH grant, R21 AI 70687. The Center for Dermatology Research is supported by an unrestricted educational grant from Galderma Laboratories, L.P.

#### References

- Corbie-Smith G, Ammerman AS, Katz ML, et al. Trust, benefit, satisfaction, and burden: a randomized controlled trial to reduce cancer risk through African-American churches. J Gen Intern Med. 2003; 18:531–541. [PubMed: 12848836]
- Corbie-Smith G, Viscoli CM, Kernan WN, et al. Influence of race, clinical, and other sociodemographic features on trial participation. J Clin Epidemiol. 2003; 56:304–309. [PubMed: 12767406]
- Corbie-Smith G, Thomas SB, Williams MV, et al. Attitudes and beliefs of African Americans toward participation in medical research. J Gen Intern Med. 1999; 14:537–546. [PubMed: 10491242]
- 4. Hartley D. Rural health disparities, population health, and rural culture. Am J Public Health. 2004; 94:1675–1678. [PubMed: 15451729]
- 5. Adams-Campbell LL, Ahaghotu C, Gaskins M, et al. Enrollment of African Americans onto clinical treatment trials: study design barriers. J Clin Oncol. 2004; 22:730–734. [PubMed: 14966098]
- Advani AS, Atkeson B, Brown CL, et al. Barriers to the participation of African-American patients with cancer in clinical trials: a pilot study. Cancer. 2003; 97:1499–1506. [PubMed: 12627515]
- Armstrong K, Calzone K, Stopfer J, et al. Factors associated with decisions about clinical BRCA1/2 testing. Cancer Epidemiol Biomarkers Prev. 2000; 9:1251–1254. [PubMed: 11097234]
- Gorkin L, Schron EB, Handshaw K, et al. Clinical trial enrollers vs. nonenrollers: the Cardiac Arrhythmia Suppression Trial (CAST) Recruitment and Enrollment Assessment in Clinical Trials (REACT) project. Control Clin Trials. 1996; 17:46–59. [PubMed: 8721801]
- 9. Bernhardt BA, Tambor ES, Fraser G, et al. Parents' and children's attitudes toward the enrollment of minors in genetic susceptibility research: implications for informed consent. Am J Med Genet A. 2003; 116A:315–323. [PubMed: 12522783]
- Jack WJ, Chetty U, Rodger A. Recruitment to a prospective breast conservation trial: why are so few patients randomised? BMJ. 1990; 301:83–85. [PubMed: 2390587]
- 11. Tangrea JA, Adrianza ME, Helsel WE. Patients' perceptions on participation in a cancer chemoprevention trial. Cancer Epidemiol Biomarkers Prev. 1992; 1:325–330.

- Braunstein JB, Sherber NS, Schulman SP, et al. Race, medical researcher distrust, perceived harm, and willingness to participate in cardiovascular prevention trials. Medicine (Baltimore). 2008; 87:1–9. [PubMed: 18204365]
- Gorelick PB, Harris Y, Burnett B, et al. The recruitment triangle: reasons why African Americans enroll, refuse to enroll, or voluntarily withdraw from a clinical trial. An interim report from the African-American Antiplatelet Stroke Prevention Study (AAASPS). J Natl Med Assoc. 1998; 90:141–145. [PubMed: 9549977]
- Freedman TG. "Why don't they come to Pike Street and ask us"?: Black American women's health concerns. Soc Sci Med. 1998; 47:941–947. [PubMed: 9722113]
- Farmer DF, Jackson SA, Camacho F, et al. Attitudes of African American and low socioeconomic status white women toward medical research. J Health Care Poor Underserved. 2007; 18:85–99. [PubMed: 17337800]
- Moutsiakis DL, Chin PN. Why blacks do not take part in HIV vaccine trials. J Natl Med Assoc. 2007; 99:254–257. [PubMed: 17393949]
- Fouad MN, Partridge E, Green BL, et al. Minority recruitment in clinical trials: a conference at Tuskegee, researchers and the community. Ann Epidemiol. 2000; 10:S35–S40. [PubMed: 11189091]
- Davis DS. Groups, communities, and contested identities in genetic research. Hastings Cent Rep. 2000; 30:38–45. [PubMed: 11475994]
- Knoppers BM, Chadwick R. Human genetic research: emerging trends in ethics. Nat Rev Genet. 2005; 6:75–79. [PubMed: 15630423]
- Reilly PR, Boshar MF, Holtzman SH. Ethical issues in genetic research: disclosure and informed consent. Nat Genet. 1997; 15:16–20. [PubMed: 8988163]
- Sharp RR, Foster MW. Involving study populations in the review of genetic research. J Law Med Ethics. 2000; 28 (1):41–51. [PubMed: 11067631]
- 22. Weijer C, Goldsand G, Emanuel EJ. Protecting communities in research: current guidelines and limits of extrapolation. Nat Genet. 1999; 23:275–280. [PubMed: 10545946]
- 23. Catz DS, Green NS, Tobin JN, et al. Attitudes about genetics in underserved, culturally diverse populations. Community Genet. 2005; 8:161–172. [PubMed: 16113533]
- 24. Flohr C, Pascoe D, Williams HC. Atopic dermatitis and the 'hygiene hypothesis': too clean to be true? Br J Dermatol. 2005; 152:202–216. [PubMed: 15727630]
- Chien YH, Hwu WL, Chiang BL. The genetics of atopic dermatitis. Clin Rev Allergy Immunol. 2007; 33:178–190. [PubMed: 18163224]
- 26. Freimuth VS, Quinn SC, Thomas SB, et al. African Americans' views on research and the Tuskegee Syphilis Study. Soc Sci Med. 2001; 52:797–808. [PubMed: 11218181]
- 27. Gross CP, Filardo G, Mayne ST, et al. The impact of socioeconomic status and race on trial participation for older women with breast cancer. Cancer. 2005; 103:483–491. [PubMed: 15597407]
- Jandorf L, Fatone A, Borker PV, et al. Creating alliances to improve cancer prevention and detection among urban medically underserved minority groups. The East Harlem Partnership for Cancer Awareness. Cancer. 2006; 107:2043–2051. [PubMed: 16977600]
- McCaskill-Stevens W, Pinto H, Marcus AC, et al. Recruiting minority cancer patients into cancer clinical trials: a pilot project involving the Eastern Cooperative Oncology Group and the National Medical Association. J Clin Oncol. 1999; 17:1029–1039. [PubMed: 10071298]
- Marshall PA, Adebamowo CA, Adeyemo AA, et al. Voluntary participation and informed consent to international genetic research. Am J Public Health. 2006; 96:1989–1995. [PubMed: 17018820]
- Buchbinder SP, Metch B, Holte SE, et al. Determinants of enrollment in a preventive HIV vaccine trial: hypothetical versus actual willingness and barriers to participation. J Acquir Immune Defic Syndr. 2004; 36:604–612. [PubMed: 15097304]
- Roberson NL. Clinical trial participation. Viewpoints from racial/ethnic groups. Cancer. 1994; 74:2687–2691. [PubMed: 7954287]
- Harris Y, Gorelick PB, Samuels P, et al. Why African Americans may not be participating in clinical trials. J Natl Med Assoc. 1996; 88:630–634. [PubMed: 8918067]

Spears et al.

- 34. Katz RV, Green BL, Kressin NR, et al. Willingness of minorities to participate in biomedical studies: confirmatory findings from a follow-up study using the Tuskegee Legacy Project Questionnaire. J Natl Med Assoc. 2007; 99:1052–1060. [PubMed: 17913117]
- Dlugos DJ, Scattergood TM, Ferraro TN, et al. Recruitment rates and fear of phlebotomy in pediatric patients in a genetic study of epilepsy. Epilepsy Behav. 2005; 6:444–446. [PubMed: 15820358]
- Robinson SB, Ashley M, Haynes MA. Attitude of African-Americans regarding prostate cancer clinical trials. J Community Health. 1996; 21:77–87. [PubMed: 8728357]
- Royal C, Baffoe-Bonnie A, Kittles R, et al. Recruitment experience in the first phase of the African American Hereditary Prostate Cancer (AAHPC) study. Ann Epidemiol. 2000; 10:S68–S77. [PubMed: 11189095]
- Katz RV, Kegeles SS, Kressin NR, et al. Awareness of the Tuskegee Syphilis Study and the US presidential apology and their influence on minority participation in biomedical research. Am J Public Health. 2008; 98:1137–1142. [PubMed: 17901437]
- Strauss RP, Sengupta S, Kegeles S, et al. Willingness to volunteer in future preventive HIV vaccine trials: issues and perspectives from three U.S. communities. J Acquir Immune Defic Syndr. 2001; 26:63–71. [PubMed: 11176270]
- 40. Gadegbeku CA, Stillman PK, Huffman MD, et al. Factors associated with enrollment of African Americans into a clinical trial: results from the African American study of kidney disease and hypertension. Contemp Clin Trials. 2008; 29:837–842. [PubMed: 18639652]
- Smith YR, Johnson AM, Newman LA, et al. Perceptions of clinical research participation among African American women. J Womens Health (Larchmt). 2007; 16:423–428. [PubMed: 17439387]
- 42. Rimer BK, Schildkraut JM, Lerman C, et al. Participation in a women's breast cancer risk counseling trial. Who participates? Who declines? High Risk Breast Cancer Consortium. Cancer. 1996; 77:2348–2355. [PubMed: 8635106]
- 43. Lichtenberg PA, Brown DR, Jackson JS, et al. Normative health research experiences among African American elders. J Aging Health. 2004; 16:78S–92S. [PubMed: 15448288]
- 44. Sengupta S, Strauss RP, DeVellis R, et al. Factors affecting African-American participation in AIDS research. J Acquir Immune Defic Syndr. 2000; 24:275–284. [PubMed: 10969353]
- 45. Bryant Borders AE, Grobman WA, Amsden LB, et al. Factors that influence the acceptability of collecting in-home finger stick blood samples in an urban, low-income population. J Health Care Poor Underserved. 2007; 18:100–115. [PubMed: 17337801]
- Lara PN Jr, Paterniti DA, Chiechi C, et al. Evaluation of factors affecting awareness of and willingness to participate in cancer clinical trials. J Clin Oncol. 2005; 23:9282–9289. [PubMed: 16361626]
- 47. Williams IC, Corbie-Smith G. Investigator beliefs and reported success in recruiting minority participants. Contemp Clin Trials. 2006; 27:580–586. [PubMed: 16839822]
- Fowler BA. An outsider's experiences in conducting field research in an African-American community. J Natl Black Nurses Assoc. 2002; 13:31–37. [PubMed: 12242748]
- Pinto HA, Caskill-Stevens W, Wolfe P, et al. Physician perspectives on increasing minorities in cancer clinical trials: an Eastern Cooperative Oncology Group (ECOG) initiative. Ann Epidemiol. 2000; 10:S78–S84. [PubMed: 11189096]
- Bates BR, Harris TM. The Tuskegee Study of Untreated Syphilis and public perceptions of biomedical research: a focus group study. J Natl Med Assoc. 2004; 96:1051–1064. [PubMed: 15303410]
- Ard JD, Durant RW, Edwards LC, et al. Perceptions of African-American culture and implications for clinical trial design. Ethn Dis. 2005; 15:292–299. [PubMed: 15825976]
- Hamilton LA, Aliyu MH, Lyons PD, et al. African-American community attitudes and perceptions toward schizophrenia and medical research: an exploratory study. J Natl Med Assoc. 2006; 98:18– 27. [PubMed: 16532974]
- 53. Lambert H, McKevitt C. Anthropology in health research: from qualitative methods to multidisciplinarity. BMJ. 2002; 325:210–213. [PubMed: 12142313]

- Morse EV, Simon PM, Besch CL, et al. Issues of recruitment, retention, and compliance in community-based clinical trials with traditionally underserved populations. Appl Nurs Res. 1995; 8:8–14. [PubMed: 7695360]
- 55. Whelton PK, Lee JY, Kusek JW, et al. Recruitment experience in the African American Study of Kidney Disease and Hypertension (AASK) pilot study. Control Clin Trials. 1996; 17:17S–33S. [PubMed: 8889351]
- 56. National Cancer Institute. [accessed July 26th, 2010] Simplification of informed consent documents. Aug 19. 2009 Available at: http://www.cancer.gov/clinicaltrials/education/ simplification-of-informed-consent-docs/allpages/print
- 57. Quandt SA, Doran AM, Rao P, et al. Reporting pesticide assessment results to farmworker families: development, implementation, and evaluation of a risk communication strategy. Environ Health Perspect. 2004; 112:636–642. [PubMed: 15064174]
- 58. Geertz C. The Javanese kijaji: the changing role of a cultural broker. 2009; 2(02):228–249.
- 59. Jezewski MA. Evolution of a grounded theory: conflict resolution through culture brokering. ANS Adv Nurs Sci. 1995; 17:14–30. [PubMed: 7778888]
- Leung MW, Yen IH, Minkler M. Community based participatory research: a promising approach for increasing epidemiology's relevance in the 21st century. Int J Epidemiol. 2004; 33:499–506. [PubMed: 15155709]
- Brody JG, Morello-Frosch R, Brown P, et al. Improving disclosure and consent: "is it safe?": new ethics for reporting personal exposures to environmental chemicals. Am J Public Health. 2007; 97:1547–1554. [PubMed: 17666695]
- Morello-Frosch R, Brody JG, Brown P, et al. Toxic ignorance and right-to-know in biomonitoring results communication: a survey of scientists and study participants. Environ Health. 2009; 8:6. [PubMed: 19250551]
- 63. Agar, MH. The Professional Stranger: An Informal Introduction to Ethnography. San Diego: Academic Press; 2009.
- 64. Bernard, H. Research Methods in Anthropology: Qualitative and Quantitative Methods. Oxford: AltaMira Press; 2009.
- LeCompte MD, Goetz JP. Problems of reliability and validity in ethnographic research. Rev Educ Res. 2009; 52:31–60.
- 66. Parker R, Ehrhardt AA. Through an ethnographic lens: ethnographic methods, comparative analysis, and HIV/AIDS research. AIDS and Behavior. 2009; 5(2):105–114.
- 67. Wolcott, H. On ethnographic intent. In: Spindler, GD.; Spindler, LS., editors. Interpretive Ethnography of Education: At Home and Abroad. Hillsdale, NJ: Erlbaum Associates; 2009.
- Halbert CH, Gandy OH Jr, Collier A, et al. Intentions to participate in genetics research among African American smokers. Cancer Epidemiol Biomarkers Prev. 2006; 15:150–153. [PubMed: 16434602]
- 69. Shavers VL, Lynch CF, Burmeister LF. Knowledge of the Tuskegee study and its impact on the willingness to participate in medical research studies. J Natl Med Assoc. 2000; 92:563–572. [PubMed: 11202759]
- Boulware LE, Cooper LA, Ratner LE, et al. Race and trust in the health care system. Public Health Rep. 2003; 118:358–365. [PubMed: 12815085]
- 71. Corbie-Smith G, Thomas SB, St George DM. Distrust, race, and research. Arch Intern Med. 2002; 162:2458–2463. [PubMed: 12437405]
- 72. Katz RV, Green BL, Kressin NR, et al. The legacy of the Tuskegee Syphilis Study: assessing its impact on willingness to participate in biomedical studies. J Health Care Poor Underserved. 2008; 19:1168–1180. [PubMed: 19029744]
- 73. Moorman PG, Skinner CS, Evans JP, et al. Racial differences in enrolment in a cancer genetics registry. Cancer Epidemiol Biomarkers Prev. 2004; 13:1349–1354. [PubMed: 15298957]
- Mouton CP, Harris S, Rovi S, et al. Barriers to black women's participation in cancer clinical trials. J Natl Med Assoc. 1997; 89:721–727. [PubMed: 9375475]
- 75. Brown DR, Topcu M. Willingness to participate in clinical treatment research among older African Americans and Whites. Gerontologist. 2003; 43:62–72. [PubMed: 12604747]

- 76. Shavers VL, Lynch CF, Burmeister LF. Racial differences in factors that influence the willingness to participate in medical research studies. Ann Epidemiol. 2002; 12:248–256. [PubMed: 11988413]
- 77. Sugarman J, Kass NE, Goodman SN, et al. What patients say about medical research. IRB. 1998; 20:1–7.
- 78. Gross D, Julion W, Fogg L. What motivates participation and dropout among low-income urban families of color in a prevention intervention? Fam Relat. 2001; 50:246–254.
- Sateren WB, Trimble EL, Abrams J, et al. How sociodemographics, presence of oncology specialists, and hospital cancer programs affect accrual to cancer treatment trials. J Clin Oncol. 2002; 20:2109–2117. [PubMed: 11956272]
- Simon MS, Du W, Flaherty L, et al. Factors associated with breast cancer clinical trials participation and enrollment at a large academic medical center. J Clin Oncol. 2004; 22:2046– 2052. [PubMed: 15082724]
- Outlaw FH, Bourjolly JN, Barg FK. A study on recruitment of black Americans into clinical trials through a cultural competence lens. Cancer Nurs. 2000; 23:444–451. [PubMed: 11128123]
- 82. Shavers VL, Lynch CF, Burmeister LF. Factors that influence African-Americans' willingness to participate in medical research studies. Cancer. 2001; 91:233–236. [PubMed: 11148585]
- Powell JH, Fleming Y, Walker-McGill CL, et al. The project IMPACT experience to date: increasing minority participation and awareness of clinical trials. J Natl Med Assoc. 2008; 100:178–187. [PubMed: 18300535]
- 84. Brandon DT, Isaac LA, LaVeist TA. The legacy of Tuskegee and trust in medical care: is Tuskegee responsible for race differences in mistrust of medical care? J Natl Med Assoc. 2005; 97:951–956. [PubMed: 16080664]
- Katz RV, Kegeles SS, Kressin NR, et al. The Tuskegee Legacy Project: willingness of minorities to participate in biomedical research. J Health Care Poor Underserved. 2006; 17:698–715. [PubMed: 17242525]
- Audrain J, Tercyak KP, Goldman P, et al. Recruiting adolescents into genetic studies of smoking behavior. Cancer Epidemiol Biomarkers Prev. 2002; 11:249–252. [PubMed: 11895873]
- Lamvu G, Lorenz C, Jonsson FM, et al. Racial differences among reasons for participating in research of pregnancy outcomes: the right from the start experience. Gender Med. 2005; 2:166– 173.
- Moore ML. Recruitment and retention: nursing research among low-income pregnant women. Appl Nurs Res. 1997; 10:152–158. [PubMed: 9274068]
- Kressin NR, Meterko M, Wilson NJ. Racial disparities in participation in biomedical research. J Natl Med Assoc. 2000; 92:62–69. [PubMed: 10800293]
- Zhu K, Hunter S, Bernard LJ, et al. Recruiting elderly African-American women in cancer prevention and control studies: a multifaceted approach and its effectiveness. J Natl Med Assoc. 2000; 92:169–175. [PubMed: 10976173]
- Moorman PG, Newman B, Millikan RC, et al. Participation rates in a case-control study: the impact of age, race, and race of interviewer. Ann Epidemiol. 1999; 9:188–195. [PubMed: 10192651]
- 92. Thompson EE, Neighbors HW, Munday C, et al. Recruitment and retention of African American patients for clinical research: an exploration of response rates in an urban psychiatric hospital. J Consult Clin Psychol. 1996; 64:861–867. [PubMed: 8916612]
- Moinpour CM, Atkinson JO, Thomas SM, et al. Minority recruitment in the prostate cancer prevention trial. Ann Epidemiol. 2000; 10:S85–S91. [PubMed: 11189097]
- 94. Stoy DB, Curtis RC, Dameworth KS, et al. The successful recruitment of elderly black subjects in a clinical trial: the CRISP experience. Cholesterol Reduction in Seniors Program. J Natl Med Assoc. 1995; 87:280–287. [PubMed: 7752281]
- 95. Sutherland HJ, da Cunha R, Lockwood GA, et al. What attitudes and beliefs underlie patients' decisions about participating in chemotherapy trials? Med Decis Making. 1998; 18:61–69. [PubMed: 9456210]

#### Questions

- **1.** How many of the studies reviewed for this article pertain to clinical dermatologic studies?
  - a. Ten.
  - **b.** None.
  - c. All.
  - d. Three.
- **2.** Knowledge of the Tuskegee Study of Untreated Syphilis was a commonly cited barrier to participation in studies that focused on:
  - a. African-Americans.
  - **b.** Multiple ethnic groups.
  - c. The general population.
  - d. The elderly.
- 3. Some of the articles reviewed in this manuscript come from:
  - a. Clinical dermatology, cardiology, oncology, and public health.
  - b. Cancer, cardiovascular disease, stroke prevention.
  - c. Stroke prevention, cancer studies, clinical dermatology.
  - **d.** None of the above.
- **4.** Principal Investigators' emphasis on minority recruitment was a significant motive for participation among studies of:
  - a. High-risk individuals.
  - **b.** Research participants and patients.
  - c. African-American women.
  - d. Healthcare providers and researchers.
- 5. Community-based participatory research involves:
  - a. Collaborative study design between scientists and participants.
  - **b.** Establishing long-term trusting relationships between researchers and participants' communities.
  - c. Research oriented toward social action for participants' communities.
  - **d.** All of the above.
- **6.** "Purposeful recruitment from all segments of the target population can address sampling biases engendered by some \_\_\_\_\_\_".
  - **a.** Community-based research strategies.
  - b. Researchers.
  - c. Research and sampling procedures.
  - **d.** Incentive programs.
- 7. "Understandable informed consent" entails \_\_\_\_\_\_.

Spears et al.

- a. HIPAA compliant language.
- b. Legally unassailable language.
- c. Technical medical language.
- d. Culturally appropriate language.
- 8. Participant-centered study schedules consider:
  - a. Participants' schedules and resources.
  - b. Participants' needs and beliefs.
  - c. Participants' values.
  - d. of the above.
- **9.** Which of the following sentences describes the relationship between cultural conflict, mistrust, and informed consent?
  - **a.** Culture conflict between researchers and participants can inhibit effective communication between the two, which breeds misunderstanding and mistrust and inhibits the ability of participants to feel informed by traditional consent processes.
  - **b.** Cultural conflict between researchers and participants is reduced by HIPAA compliant, informed consent processes, which also reduces the mistrust felt by participants for researchers.
  - **c.** Mistrust of researchers by participants results in cultural conflict, which can be remedied by the informed consent process.
  - **d.** Traditional informed consent processes cause cultural conflict between researchers and participants, which results in a legacy of participant mistrust.
- **10.** The authors conclude that clinical dermatologic research could benefit from additional research and assessment of:
  - **a.** Participation motives and barriers among rural populations.
  - **b.** Participation motives and barriers among infants and young children.
  - c. Recruitment barriers and solutions within clinical dermatologic research.
  - **d.** All of the above.

#### Answers to questions

- b
  b
- **3.** b
- **4.** d
- 5. d
- **6.** a
- **7.** d
- **8.** d

Spears et al.

**9.** a

**10.** d

_
_
<u> </u>
- U
20
D
-
~
-
C
-
_
-
0
utho
Ξ,
ž
2
2
2
2
2
2
2
r Manu
r Manu
r Manus
r Manu
r Manus

Table 1

Distribution of reviewed articles by population emphasized

	Number and percent of all	of all articles						
Total number of articles African-Americans Mult	African-Americans	Multiple ethnic groups	Women	General population	Healthcare I tiple ethnic groups Women General population Research participants Patients High risk researchers	Patients	High risk	Healthcare providers and researchers
78 (100%)	24 (31%)	10 (13%)	10 (13%) 9 (12%)	9 (12%)	5 (6%)	10 (13%)	10 (13%) 4 (5%) 6 (8%)	6 (8%)

Spears et al.

NIH-PA Author Manuscript

Table 2

Common barriers to participation in research by population studied

Number and percent of all qualifying articles

Spears et al.

Barriers	All articles (%)	All articles (%) African-American	Multiple ethnic groups	Women	General population	General population Research participants	Patients	High risk	Healthcare providers and researchers
Mistrust research	25 (32.0)	$12^{3,13,14,16,26,33,37,41,44,52,68,69}$	517,50,70–72	315,73,74	2 <sup>75,76</sup>	1 <sup>31</sup>	177	0	1 <sup>29</sup>
Lack of access to research	13 (16.6)	214.33	2 <sup>28,32</sup>	2 <sup>27,73</sup>	1 <sup>78</sup>	2 <sup>79,80</sup>	1 <sup>46</sup>	0	329,49,81
Culturally incompetent research design	12 (15.3)	33.14,82	228,50	315,73,74	1 <sup>76</sup>	0	0	0	329,54,83
Lack of time	11 (14.1)	233,41	2 <sup>17,28</sup>	$2^{2,73}$	1 <sup>78</sup>	1 <sup>31</sup>	1 <sup>35</sup>	1 <sup>39</sup>	1 <sup>83</sup>
Lack of information about research	10 (12.8)	416,26,33,41	317,28,32	0	0	0	1 <sup>12</sup>	0	2 <sup>49,83</sup>
Low-SES	10 (12.8)	56,30,33,36,37	1 <sup>28</sup>	$1^{27}$	0	179	2 <sup>12,46</sup>	0	0
Mistrust of the medical community	10 (12.8)	43.14.16.36	317,70,71	1 <sup>15</sup>	184	0	0	0	1 <sup>49</sup>
Guinea Pig Fear Factor	9 (11.5)	313,16,37	332,34,85	1 <sup>15</sup>	0	0	1 <sup>12</sup>	0	1 <sup>83</sup>
Fear of tests and procedures	7 (8.9)	43.16.26.40	117	$1^{10}$	0	0	1 <sup>35</sup>	0	0
Fear of side effects	5 (6.4)	136	0	12	0	1 <sup>31</sup>	0	2 <sup>11,39</sup>	0
Fear of genetic research	5 (6.4)	2 <sup>37,68</sup>	0	0	1 <sup>86</sup>	0	1 <sup>23</sup>	19	0
Fear of new medical knowledge	3 (3.8)	0	0	0	0	0	1 <sup>23</sup>	2 <sup>9,39</sup>	0
Social disapproval for participation	3 (3.8)	213,16	0	0	0	0	0	1 <sup>39</sup>	0
Knowledge of Tuskegee Study of Untreated Syphilis	2 (2.5)	0	0	0	2 <sup>38,75</sup>	0	0	0	0

**NIH-PA** Author Manuscript

NIH-PA Author Manuscript

# Table 3

Common motives for participation in research by population studied

	00 01.00	
	DUIVING UND	
	2	
•	noron n	
	Vumber or	

Spears et al.

Motives	All articles (%)	African-American	All articles (%) African-American Multiple ethnic groups Women General population Research participants Patients	Women	General population	Research participants	Patients	High risk	providers and researchers
Receipt of some benefit	16 (20.5)	81,13,26,40,41,52,68,82	0	2 <sup>87,88</sup>	2 <sup>45,78</sup>	0	2 <sup>8,89</sup>	2 <sup>11,39</sup>	0
Opportunity to help others	11 (14.1)	$7^{13,16,26,40,43,52,82}$	0	$1^{15}$	0	1 <sup>31</sup>	0	2 <sup>9,39</sup>	0
Culturally competent research design	7 (8.9)	437,41,52,90	1 <sup>32</sup>	1 <sup>91</sup>	0	0	1 <sup>92</sup>	0	0
Being at high risk for some health problem	6 (7.6)	313,40,44	0	2 <sup>7,87</sup>	0	0	0	1 <sup>42</sup>	0
Trust of researchers	6 (7.6)	2 <sup>36,43</sup>	0	188	345,78,93	0	0	0	0
Relevance of topic	5 (6.4)	2 <sup>26,41</sup>	0	$2^{2,73}$	1 <sup>45</sup>	0	0	0	0
Participant-centered study schedule and procedure	4 (5.1)	1 <sup>90</sup>	0	0	245,78	0	18	0	0
Possible disease prevention	3 (3.8)	0	0	0	0	0	$1^{23}$	2 <sup>9,39</sup>	0
Awareness of/access to research	2 (2.6)	0	0	0	0	1 <sup>79</sup>	1 <sup>46</sup>	0	0
Perceived low risk	2 (2.6)	0	0	0	0	0	0	2 <sup>9,39</sup>	0
PI emphasis on minority recruitment	1 (1.3)	0	0	0	0	0	0	0	1 <sup>47</sup>

**NIH-PA** Author Manuscript

Commonly suggested solutions to increase recruitment of underserved populations to research by population studied

Number and nercent of all qualifying articles

Spears et al.

									Healthcare
Solutions	All articles (%)	African-American	Multiple ethnic groups	Women	General population	Research participants	Patients	High risk	providers and researchers
Culturally competent research design	16 (20.5)	713,14,26,33,41,51,69	2 <sup>28,50</sup>	2 <sup>74,91</sup>	0	0	1 <sup>92</sup>	0	429,47,54,81
Community-based recruitment	15 (19.2)	86,14,16,33,41,48,52,55	1 <sup>17</sup>	2 <sup>2,91</sup>	376,93,94	0	0	0	$1^{81}$
Efforts to build and increase trust	15 (19.2)	93,13,14,16,33,37,43,48,52	2 <sup>32,71</sup>	$1^{15}$	345,93,94	0	0	0	0
Understandable informed consent	15 (19.2)	86,13,14,26,30,36,51,68	117	0	1 <sup>86</sup>	0	277,95	19	2 <sup>29,81</sup>
Conduct educational programs to inform communities about projects	13 (16.6)	416,36,40,52	2 <sup>32,50</sup>	0	193	180	1 <sup>46</sup>	1 <sup>39</sup>	329,49,83
Participant-centered study schedule and procedures	11 (14.1)	414,33,37,43	317,28,32	0	2 <sup>45,78</sup>	0	1 <sup>35</sup>	0	1 <sup>29</sup>
Increased physician participation and access to research	6 (7.6)	2 <sup>36,55</sup>	0	0	0	1 <sup>80</sup>	0	0	3 <sup>29,49,83</sup>
Provision of monetary and non- monetary benefits	6 (7.6)	56,26,36,52,68	0	1 15	0	0	0	0	0
Address and overcome socioeconomics barriers	5 (6.4)	1 <sup>43</sup>	0	$1^{27}$	2 <sup>78,86</sup>	0	0	0	1 <sup>29</sup>
Incorporation of target population at all levels of research design and implementation	5 (6.4)	337,51,52	150	115	0	0	0	0	0
Emphasis on follow-up counseling	1 (1.3)	0	0	0	0	0	0	19	0