Building Trust for Engagement of Minorities in Human Subjects Research: Is the Glass Half Full, Half Empty, or the Wrong Size?

"An optimist will tell you the glass is half-full; the pessimist, half-empty; and the engineer will tell you the glass is twice the size it needs to be."
—*Oscar Wilde*

In 1972, the longest running nontherapeutic research study ever conducted by our Public Health Service ended. The Tuskegee Study of Untreated Syphilis in the Negro Male (1932–1972) enrolled 399 poor, African American men with syphilis, watched as their syphilitic disease progressed, misled them, and denied them treatment. As one survivor said when President Bill Clinton apologized for the study:

> We were treated unfairly and to some extent like guinea pigs. We were not pigs. . . . We were all hard working men, not boys, and citizens of the United States. The wounds that were inflicted upon us cannot be undone. . . . I am saddened today to think of those who did not survive and whose families will forever live with the knowledge that their death and suffering was preventable.[1]

In 1974, in the aftermath of Tuskegee, Congress passed the National Research Act (Pub. L. No. 93-348), creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research as well as US federal regulations providing, for the first time, formal oversight of research with human participants. The Belmont Report, perhaps the most enduring legacy of the Commission, outlined three ethical principles to guide human research, and imposed new requirements for independent institutional review board assessment to ensure that research was (1) consistent with these principles,

Tabatha Holley, aged 19 years, of Dawson, GA, looks at the sign she just made before joining a march in protest the day after George Zimmerman was found not guilty in the 2012 shooting death of unarmed African American teenager Trayvon Martin. Photograph by David Goldman. Printed with permission of AP Images.

(2) reasonable with regard to risks and benefits, (3) had appropriate informed consent procedures, and (4) involved vulnerable groups only with justification and appropriate safeguards.[2]

The Belmont principles mark an historical shift in articulating a national commitment to protecting "vulnerable populations" in research. The Belmont Report cautions that "groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized" should be "protected against . . . being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition."[2(p10)] History already had demonstrated that these populations could be exploited by research, and ethics needed to ensure they were not unwittingly included in scientific

pursuits that might compromise their well-being.

While such protection is essential, little attention was given in regulatory oversight of other important interests these same protected populations may have in the context of research. By the mid-1980s, concerns began to surface that such "protection" may itself lead to unintended harm, with minority and other populations voicing concern that their underrepresentation in research meant their communities were not reaping the health benefits of research. Due in large measure to the advocacy of the women's health movement and HIV/AIDS advocates, these concerns ushered in a new era whereby the National Institutes of Health (NIH) mandated the inclusion of women and racial and ethnic minorities in research in 1994,[3] followed a few years later by a mandate for

the fair inclusion of children.[4] Soon the third Belmont principle, the concept of justice in research ethics, was invoked to require both protection *from* research related risks, AND access *to* research related benefits for populations who might sometimes be forgotten.[5]

We find ourselves, therefore, with many reasons to see the research ethics glass as half full. US researchers today know that human participant research must undergo independent review before a study can proceed and must include participants only with their informed consent, and that they must complete mandated ethics training.[6] In the context of research with racial and ethnic minorities, there also are reasons for being optimistic. The NIH mandate has become more fully realized as institutions have focused on strategies to increase adherence to it, including requiring hypothesis testing by subgroup and consideration of minority enrollment in the impact score when grant proposals are reviewed.[7,8] Additionally, promising data indicates that minorities are willing to participate in research across a spectrum of risk and invasiveness.[9] Furthermore, the NIH is increasingly requiring evidence of community engagement as a condition of funding, including mandated community cores in numerous comprehensive center grants, such as the Clinical Translation Science Awards[10] and program announcements for community-based participatory research by various NIH institutes.[11] The Patient Centered Research Outcomes Institute, funded significantly through the federal Affordable Care Act (Pub. L. No. 111-148), similarly requires "stakeholder engagement" for most of its research.

And yet, we also see some reason to call the research ethics glass "half empty" as highlighted by growing recognition that the simple inclusion of racial and ethnic minorities is not itself sufficient. Without parallel attention to the context and means by which we, as researchers, invite, include, and involve individuals and minority communities in our research, we will not be fulfilling the Belmont edicts of respect and avoidance of harm.[12,13] Sadly, too much research attention is targeted to how to get minority communities to say yes to our studies rather than focusing on how researchers or research institutions should behave, and the extent to which we are trustworthy and capable of fostering openness to research.

The era of "community" as research partner is nonetheless maturing and increasingly legitimized. In this context, our current situation perhaps best approximates a "glass of the wrong size," as NIH's mandates for inclusion of women and minorities, coupled with the changing demographics of our society, demand that researchers create innovative and effective strategies to recruit and retain minorities in clinical trials. Community engagement may well be a strategy to navigate this challenge, yet the expectation for community engagement remains inconsistent from agency to agency, and the requirement for "community cores"—when they exist—changes over time. Furthermore, until commitments to community interests in the context of research are as foundational as research ethics commitments to individual participants, the burden of building community trust and engagement will remain solely with individual investigators who will lack the institutional support

needed both to assist new investigators going forward and for sustainability after grant funding has ended.

Although the technical training of our researchers is superb, less attention focuses on preparing researchers to work ethically and effectively in communities from whom they often differ by race, ethnicity, social class, and culture. While researchers learn the scientific method and that objectivity is key to integrity of the results, community engagement may require us to adjust our methods, approach, and sometimes even the questions we are asking. Moreover, demonstrated proficiency in scientific methodology cannot be assumed to include the interpersonal skills and humility needed to work effectively with diverse communities. We have every reason to assume that most researchers are sympathetic to the health issues of racial and ethnic minority communities; and yet, just like with other research methods, formal training in engagement, recruitment, retention, and interactions must be conducted, and must emphasize the knowledge, skills, and attitudes that can enable us to become "self-reflective researchers"—researchers who develop the "cultural confidence" to say when we do not know, and to willingly examine our own biases and prejudices.[14] This novel type of training fosters the ability to recognize that being well intentioned may not be sufficient and that learning the stories, the background, the concerns, and the priorities of other groups, our partners, may be central to our being a good partner ourselves, and enables us to ask ourselves and our institutions critical questions.

The articles in this issue provide evidence of a "glass half full, half empty, and of the wrong size." Many of these articles echo the challenges inherent in the complex issues associated with the ethical treatment of underrepresented, minority, and vulnerable populations in research. Some challenge the idea of what it means to be a vulnerable population and raise new ideas about how we should think about the words "minority" and "vulnerable." Others explore the unique concerns about the ethical inclusion of Native American and Alaska Native populations, and the growing attention researchers are now giving to the protection of communities in addition to the protections of individuals who are involved in research. Several articles highlight the need for increased training of researchers and health professionals designed to increase their capacity to ethically engage minority or vulnerable communities. Some tackle the issues of past research abuses and mistrust and provide insight on how researchers can move forward and build trusting relationships. In others, we find successful strategies, suggestions of best practices for community engagement, and an overview of the state of the field. Together, the articles illustrate the breadth and variety of concerns related to ethical human participant research and highlight the growing awareness that a one-size-fits-all approach to ethical inclusion is insufficient to address the many factors that can impact an individual or community's experience of research. Rather, these articles point to the need for creative approaches despite an environment of standardizing, streamlining, and maximizing efficiency. This rich discussion reflects the growing

complexities of communities defined by immigrant status, degree of disability, tribal status, or racial group, while also articulating different strategies for respect, promotion of agency, protection from harm, and achievement of fair share of benefits, enabling us to reengineer the shape of the glass to one in which racial and ethnic minorities are active participants in a research enterprise that is ethical, trustworthy, and scientifically sound. ∎

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