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

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“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 non-therapeutic research study ever conducted by our Public Health Service ended. The *knowledge that their death and suffering was preventable.*⁹

1)

In 1974, in the aftermath of Tuskegee, Congress passed the National Research Act, creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research as well as U.S. federal regulations providing, for the first time, formal oversight of research with human subjects. 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 (IRB) assessment to ensure that research was 1) consistent with these principles, 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 *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) (p.10) 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.

engagement remains inconsistent from agency to agency, and the requirement for “community cores” –when they exist-- changes over time. Further, 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 (12). This novel type of training fosters the ability to recognize that being well intentioned may not be sufficient; 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 Alaskan 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 papers 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 subjects 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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