Rethinking the Vulnerability of Minority Populations in Research

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The Belmont Report, produced in 1979 by a United States government commission, includes minority populations among its list of vulnerable research participants. In this article, we consider some previous attempts to understand the vulnerability of minorities in research, and then provide our own account.

First we examine the question of the representation of minorities in research. Then we argue that the best understanding of minorities, vulnerability, and research will begin with a broad understanding of the risk of individual members of minority groups to poor health outcomes. We offer a typology of vulnerability to help with this task.

Finally, we show how researchers should be guided by this broad analysis in the design and execution of their research. (*Am J Public Health.* 2013;103:2141–2146. doi:10.2105/AJPH.2012.301200)

THE CONCEPT OF "VULNERA-bility" is used in research ethics to signify that those identified as vulnerable need extra protections over and above the usual protections offered to participants in research.[1–3] Various types of vulnerability have been identified,[4,5] and the lists of those considered vulnerable regarding research participation is now extensive.[6,7] Despite these measures, there is ongoing concern that identifying groups or individuals as vulnerable can trigger paternalism and stereotyping,[8] and that protecting vulnerable groups by excluding them from research may do more harm than good.[9] In this article we argue that ethical engagement of minority populations in research requires, among other things, a better understanding of what is meant by "vulnerable" in this context, and we offer an account of vulnerability that provides practical guidance to those wishing to perform research with minority populations.

VULNERABILITY IN HUMAN RESEARCH ETHICS GUIDELINES

The Belmont Report was the first human research ethics guideline to specifically identify vulnerable groups "such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized."[2(p12)] The Belmont Report drew attention to those who might be vulnerable to exploitation and overrepresentation in research, because of their dependent status, impaired or absent capacity to give informed consent, or location in institutions and health care settings where research was likely to occur. Although Nazi war experiments were seen as exemplars of unethical research, Beecher had identified similar breaches in US research.[10] The Belmont Report offered protections against the use in research of individuals or groups without their understanding, consent or any likelihood of benefit, with an emphasis on protecting the vulnerable from unjust research participation.

Despite its strong stand on research with vulnerable groups, the Belmont Report failed to distinguish different sources or kinds of vulnerability or to map particular protections to particular vulnerabilities. This is a problem because different kinds of vulnerability warrant different responses. Nickel argues that there are 2 overlapping senses of vulnerability at work in the Belmont Report and in subsequent human research ethics guidelines.[11] The first relates to the capacity to give informed consent, which the Belmont Report connects to the principle of respect for autonomy. Given the history of research performed without consent, this concern is certainly justified. However, the desire to protect those who lack competence to give consent can lead to an undue focus on consent as the sole or major remedy for vulnerability with subsequent neglect of other morally salient features of research.[12–14] The second sense of vulnerability identified by Nickel relates to the Belmont Report's principle of justice, by which it means fairness. The concern here is twofold: first, vulnerable groups may be overrepresented in research, for example where they lack the understanding or power to refuse participation; this is explicit in the Belmont Report. Second, Nickel claims that vulnerable groups may be excluded from research and thereby be excluded from the benefits of participation in clinical trials and subsequent access to treatments for which research evidence exists.[11,15]

Recent scholarship on vulnerability in research ethics has focused on the problem of labeling individuals or groups as vulnerable in ways that fail to consider different sources or kinds of vulnerability.[8] For example, labeling minority populations as vulnerable does not account for educational and other salient differences that exist within minority populations, and which affect individuals' capacity to give informed consent, or comply with research protocols. Research ethics guidelines that simply list groups likely to be vulnerable run a risk of stereotyping, and of the subsequent harms of unjustified exclusion from research.

VULNERABILITY OF MINORITY POPULATIONS

Minority populations are typically included in lists of the

vulnerable in research, and this is reflected in community views that race/ethnicity is a source of vulnerability.[16] It is therefore important to investigate the specific vulnerabilities associated with minority populations' involvement in research, including under- and overrepresentation.

Underrepresentation of minority populations in research is a well-recognized phenomenon[17,18] that leads to a number of problems. These include a lack of information about ethnicity and health, a potential lack of applicability of evidence generated from clinical trials to minority populations, and a subsequent decreased access to interventions and relative undertreatment.[18] Given higher rates of morbidity and mortality among ethnic minorities in comparison with majority populations,[19] this lack of representation in research exacerbates the existing vulnerability of minorities to poor health outcomes. It is therefore worth taking a look at the issue of underrepresentation and what accounts for it.

Underrepresentation has variously been attributed to: unwillingness of minorities to participate in research for a range of reasons, lack of opportunity, medical ineligibility, circumstantial reasons such as lack of flexibility in childcare or employment preventing participation in research, and lack of relevant cultural understandings on the part of researchers.[20,21] There is a widespread belief that

> racial and ethnic minority groups in the United States, especially African Americans, are less willing than non-Hispanic Whites to participate in health research.[20(p0202)]

In particular, lack of participation in research by African Americans is linked to alleged distrust of health research in the aftermath of the Tuskegee syphilis study, just as the recent misuse of blood samples taken from the Havasupai Tribe has exacerbated mistrust among Native Americans.[22,23] However, the research by Wendler et al. into the enrollment of 70 000 individuals into 20 trials conducted from the mid 1980s to early 2000s indicates that African American and Hispanic minorities are as willing to participate in research as non-Hispanic Whites.[20] For some kinds of clinical and surgical intervention research, African Americans and Hispanics are more likely than non-Hispanic Whites to participate in research if invited. Rather than mistrust leading to lack of participation, this research indicates that minority groups are underrepresented in research because they are not offered the opportunity to participate. For example, in a trial comparing 2 different treatments for coronary artery disease, 3823 non-Hispanic Whites were offered enrolment, compared with 16 individuals from all minorities combined.[20] We note that the implementation of the National Institutes of Health Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research, which mandates inclusion of minorities in research falling under this policy, aims to address this issue.

We know a little about the reasons why researchers fail to invite minority groups into research, and about the perceived barriers to participation.[24] Ranganathan and Bhopal, in their review of cardiovascular cohort studies, found that some studies specifically excluded minorities, although others used recruitment methods, occupation-based or geographic, that tended, perhaps unwittingly, to exclude minorities.[17] They postulate that ethnic- or race-based exclusions may be explained by factors including

> scientific pragmatism, shortage of resources, potential difficulties in accessing populations and in gaining informed consent, insufficient expertise and experience, lack of interest, a resistance to dividing populations by ethnic or racial status (particularly in some countries of mainland Europe), and the possibility of indirect or direct discrimination.[17(p0334)]

Research into recruitment of minority groups lends support to at least some of these reasons. Samsudeen et al. found that personal relationships and fluency in the relevant first language of the minority group were factors associated with success in recruitment of South Asians into a prevention trial for diabetes; conversely, reasons given for failing to recruit South Asians included lack of time, a belief that the relevant patients would not be interested or that the invitation to participate would not be appropriate, or lack of interest on the part of potential participants.[24] The belief that an individual would not be interested in participating in research may be attributed to stereotyping, which in turn may rest upon the erroneous view about the unwillingness of minority populations to participate in research.

How does this information about involvement of minorities in research relate to the research ethics guidelines' identification of minorities as vulnerable? Labeling a group or population as vulnerable signals that extra care must be taken, but unless the researchers know that lack of opportunity is the main barrier to participation, their efforts to take care may be misguided. It seems that concerns about exploitation leading to unfair overburdening of minorities with research are unfounded. The Belmont Report aimed to protect those who lacked sufficient power or status to decline participation in research. However, the problem appears to be the opposite: minority populations are not offered an equal opportunity to participate in research.

However, there is a particular area of research in which minority groups are overrepresented, and this may be an example of the kind of vulnerability against which the Belmont Report intended to protect. Phase I trials usually recruit healthy volunteers, with the aim of finding out whether the intervention under investigation is safe in humans. In a review of phase I trials, Fisher and Kalbaugh found that 63.9% of participants were non-White, and of these, 22.3% were African American and 36.8% were Hispanic.[25] The relative proportions in the US population of African Americans and Hispanics are 12.4% and 15.8% respectively. Participation in phase I trials is

recognized to be risky and without potential therapeutic benefit for participants. For these reasons, participants are paid, in what is known as guinea-pigging.[26] This kind of involvement in research raises questions about vulnerability to exploitation of those, who are as the Belmont Report puts it, "easy to manipulate as a result of their illness or socioeconomic condition."[2(p12)] The issue of whether payment for participation in phase I trials amounts to coercion has been vigorously debated in the bioethics literature.[27–29] Some claim that remuneration for risky activities is a noncontroversial feature of the employment market, and that the opportunity to earn an income from participating in trials is no worse than paying people to do other potentially dangerous or unpleasant tasks.[30] On the other hand, those who make a living from trials are some of the most disenfranchised of US residents, the conditions of research trial participation fall well short of regular employment conditions, there are risks of severe adverse health consequences, and there is likely a lack of therapeutic access to the medications being trialled.[26]

Aside from issues to do with over- or underrepresentation in research, lack of capacity to give adequate informed consent is identified as a primary way in which vulnerable groups may be unable to protect their own interests. Clearly it is morally wrong to involve people in research without their consent or that of a legally mandated guardian or equivalent. Informed consent is a fundamental requirement of ethical research. But as noted earlier, this concern is not identified as a specific vulnerability of minority groups in research. And clearly, there is no reason why members of minority populations should be considered less able to give informed consent than members of majority populations. Best practice may involve the use of a range of information and recruitment materials in relevant languages to communicate effectively, but once effective communication is achieved, there can be no suggestion that minority groups lack capacity to consent. However, we note that the individualistic focus of the informed-consent process runs counter to cultural traditions within some minorities such as indigenous populations, who may prefer a community-based approach to decisions about participation in research.[31]

Minority populations are not necessarily vulnerable in the ways flagged in research ethics guidelines such as the Belmont Report, but nonetheless, there are significant vulnerabilities experienced by minorities in relation to research. These relate principally to exclusion leading to lack of evidence about and potential lack of access to effective medications, and exploitation in relation to phase I trials. However, in thinking about research-related vulnerability, we do not start with a blank slate. We have to assess past wrongful inclusions and exclusions from research that were based upon race or ethnicity, and we also have to take account of significant health disparities experienced by minorities. Thus, to engage fully with the notion of vulnerability as it relates to minorities in research, we propose the following typology of vulnerability.

A PRACTICAL APPROACH TO VULNERABILITY

To identify and address research-related vulnerabilities experienced by minorities, we start by considering the sources of vulnerability in general. There are 3 such sources: inherent, situational, and pathogenic.[32] Inherent vulnerabilities are shared by all humans. These stem from our embodiment and our affective and social nature. They include vulnerability to injury and death, and to psychological ills like loneliness or lack of self-respect. Situational vulnerabilities, by contrast, come into being in specific economic, social, or political contexts that vary from person to person, and may exacerbate or ameliorate inherent vulnerabilities. For example, earning an income alleviates vulnerability to hunger. Pathogenic vulnerabilities are situational vulnerabilities that occur because of adverse social phenomena. They include vulnerabilities caused by injustice, domination, and repression, and also those that occur when actions intended to alleviate vulnerability actually make it worse. So the vulnerability to discrimination that affects minority populations is pathogenic, as is the vulnerability incurred by a person with disabilities who is put in the power of a malicious or incompetent caregiver and thereby made worse off.

All of these vulnerabilities—inherent, situational, and pathogenic—may be occurrent or dispositional. Although vulnerability is defined in terms of a potential to incur a harm or wrong, some harms and wrongs are much more likely than others. Occurrent vulnerabilities refer to very likely outcomes, such as a homeless person's vulnerability to theft or injury. Dispositional vulnerability refers to potential outcomes, such as a pregnant women's vulnerability to complications in labor, which may or may not eventuate. Dispositional vulnerabilities can become occurrent under certain conditions.

Using this typology, we can now classify the vulnerabilities of a member of a racial or ethnic minority group. In the United States, racial and ethnic minorities, such as African Americans, Hispanics or Native Americans/Alaska Natives, are at greater risk than average for a range of negative health outcomes.[33,34] Although all of the mechanisms for this disparity are yet to be fully mapped, it is clear that inherent, situational, and especially pathogenic sources of vulnerability play a role in explaining it. First of all, there is evidence that members of minority groups may have inherent vulnerabilities, based on genetics, to particular diseases or health outcomes. For instance, African Americans are at greater risk for sickle-cell anemia than members of the general US population.[35]

Still, most individuals have their share of distinctive genetic risks, and thus the inherent

vulnerabilities of minorities cannot alone account for health disparities between minorities and the general population. Many vulnerabilities of minorities are instead situational and, especially, pathogenic. Here we emphasize that these are vulnerabilities individual minorities are more likely to have, but do not have necessarily. Overall, African Americans and Hispanics in the United States have a lower socioeconomic status (SES) than Whites.[36] Measures of SES combine measures of income, education, and employment, all of which may be sources of situational vulnerability. Differences in SES have been shown to predict health disparities.[19] Pathways by which SES affects health outcomes are various and remain under investigation. Some are obvious: being poor or unemployed increases one's vulnerability to illness and death by increasing risk factors for ill health such as stress or malnutrition, and by decreasing one's access to health care, especially in the United States where health insurance is most often provided by employers. But researchers have cautioned against the "medicalization" of health outcomes.[37] Broader social factors influence health outcomes as much as the availability and quality of health care, and may partly explain the correlation between SES and health outcomes. Finally, insofar as the difference in SES between certain minorities and Whites is caused by past and present injustice and discrimination, minority vulnerabilities to poor health are pathogenic.

This classification of minority vulnerability can be used to identify the obligations that ensue in research with minority populations. These obligations are broader than those related solely to the ethical conduct of research, as our account directs attention to the causes of vulnerability experienced by minorities. The first set of duties relates to the research agenda and the duty to look at all sources of vulnerability in health research with minority populations. The second set of duties relates to ethical conduct in the context of individual research projects.

In relation to the first set of duties, the ideal minorities health research program in the United States would mitigate the inherent vulnerability of minorities and reduce or eliminate their situational vulnerabilities, especially those that are pathogenic. It would ask what factors make or prevent dispositional vulnerabilities from becoming occurrent. Health research with these goals would include but not be confined to medical research traditionally understood. Other forms of research might investigate interventions unrelated to health care, such as direct income support, or antidiscrimination programs in schools. Research should explore factors which affect disparities other than health care access, thus avoiding "medicalization"[37] and guiding more holistic health policy.[38]

Moreover, such research should address specific sources of vulnerability in minority populations, rather than taking the vulnerability of minority groups to be homogenous. For example, although low literacy is a risk factor for poor health, and African Americans have increased rates of low literacy, research which specifically targets literacy is preferable to research that targets minorities as illiterate. Rothman et al. have shown that individualized instruction can help patients with poor literacy achieve improved outcomes in the management of their type 2 diabetes.[39] Because a specific cause of racial disparity in diabetes care is health literacy, this study addressed a source of minority vulnerability but avoided stereotyping African Americans as illiterate. Measures that look at specific vulnerabilities associated with minorities rather than stereotyping individuals, provide a nonstigmatizing way to include more members of minority populations in research.

In terms of prioritizing the research agenda, we believe that interventions that address pathogenic causes of disparities should receive urgent attention. Thus research is required into interventions for preventing discrimination and racism, as these are implicated in the genesis of minority populations' health disparities.[19,40]

On our account, the overinclusion of minorities in phase I research is pathogenic as it exploits those who are unable to access alternative ways of earning money, and exposes them to increased risk of harms. In an ideal world, participants would have viable options in relation to employment or income support. But given the current sociopolitical landscape, the main way in which the vulnerability of those enrolling in phase I trials can be reduced is to improve conditions for participants. This could be achieved by providing clinical trial insurance or compensation for trial-related injuries.[41]

The second set of vulnerability-related duties falls to researchers once individual research projects have been designed. Researchers have obligations to identify and put in protections against specific vulnerabilities of participants that may be caused by the research, in ways that take account of the participants and the context. For instance, if literacy issues jeopardize informed consent, researchers should find alternative ways to communicate the research goals to the participants and seek their consent, rather than avoiding enrolling members of groups known to have high rates of illiteracy. As with the overall research program, pathogenic vulnerabilities should be avoided. The Tuskegee Syphilis Experiment provides a vivid example of research generating pathogenic vulnerability. The experiment began as an attempt to identify differences in the course of syphilis among African American men by studying the progress of the disease. The study continued after the discovery of penicillin as a cure for syphilis, and researchers went out of their way to hide from participants the fact that they had the disease.[22] This strategy increased vulnerability in the population researchers originally intended to help. Although informed consent should prevent this kind of abuse in the present, researchers should also make sure that paternalism and protections do not increase vulnerability in other

ways. Minorities should not, for instance, be excluded from potentially beneficial research simply because the researcher assumes they are not interested.

CONCLUSIONS

From the time of the Belmont Report, research ethics has treated ethnic and racial minorities as examples of vulnerable populations. Guided by the Belmont Report, treatments of minority vulnerability have focused on mandating informed consent and protecting against the exploitation and over-representation of minorities in research. But precisely identifying the nature, source, and best response to minority vulnerability has been more difficult. We suggest that understanding the vulnerability of minority research participants should begin with examining the vulnerabilities minorities have to poor health outcomes. This process can be guided by the typology of vulnerability we offer. Aided by this understanding, we propose that researchers have an obligation to design and implement research that mitigates inherent vulnerability and works to eliminate pathogenic vulnerability. In so doing, they should take care to respect research participants, and avoid generating additional pathogenic vulnerabilities through the research itself. ■

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This article was accepted December 21, 2012.

Contributors

W. Rogers drafted the introductory paragraph and the first 2 sections of the article. M. M. Lange drafted the third section of the article and the Conclusions, with feedback from W. Rogers, with both authors approving the final submission. Both authors collaborated to revise the article after receiving feedback from anonymous reviewers.

Acknowledgments

This article forms part of the research project "Autonomy, Vulnerability, and Justice," funded by an Australian Research Council grant (DP110102272). The funders had no control over or input into the research.

Human Participant Protection

No institutional review board approval was needed for this article because it did not involve human participants.

References

1. World Medical Association. 2008. Declaration of Helsinki. Available at: http://www.wma.net/en/30publications/10policies/b3/. Accessed 15 Oct 2012.

2. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* Washington, D.C.: Department of Health, Education, and Welfare; 1979.

3. Council for International Organizations of Medical Sciences. International ethical guidelines for biomedical research involving human subjects. 2002. Available at: http://www.cioms.ch/publications/layout_guide2002.pdf. Accessed October 15, 2012.

4. Kipnis K. Seven vulnerabilities in the pediatric research subject. *Theor Med Bioeth.* 2003;24(2):107–120.

5. Rogers W, Ballantyne AJ. Special populations: Vulnerability and protection. *RECIIS Electron J Commun Inf Innovation Health.* 2008;2(suppl 1):S30–S40.

6. Office of Human Research Protection (OHRP). Code of Federal Regulations for the Protection of Human Subjects. Available at: http://www.hhs.gov/ohrp/policy/ohrpregulations.pdf. Accessed December 17, 2012.

7. Hurst SA. Vulnerability in research and health care; describing the elephant in the room? *Bioethics.* 2008;22:191–202.

8. Luna F. Elucidating the concept of vulnerability: Layers not labels. *Int J Fem Approaches Bioeth.* 2009;2:121–139.

9. Lyerly AD, Little MO, Faden R. The second wave: Toward responsible inclusion of pregnant women in research. *Int J Fem Approaches Bioeth.* 2008;1(2):5–22.

10. Beecher HK. Ethics and clinical research. *N Engl J Med.* 1966;274:1354–1360.

11. Nickel PJ. Vulnerable populations in research: the case of the seriously ill. *Theor Med Bioeth.* 2006;27:245–264.

12. Bielby P. *Competence and Vulnerability in Biomedical Research.* New York: Springer; 2008.

13. Levine C, Faden R, Grady C, et al. The limitations of "vulnerability" as a protection for human research participants. *Am J Bioeth.* 2004;4(3):44–49.

14. Macklin R. Bioethics, vulnerability and protection. *Bioethics.* 2003;17:472–486.

15. Rogers WA. Evidence-based medicine and justice: a framework for looking at the impact of EBM on vulnerable or disadvantaged groups. *J Med Ethics.* 2004;30:141–145.

16. Chiu CT, Katz RV. Identifying the "vulnerables" in biomedical research: The vox populis from the Tuskegee Legacy Project. *J Public Health Dent.* 2011;71(3):220–228.

17. Ranganathan M, Bhopal R. Exclusion and inclusion of nonwhite ethnic minority groups in 72 North American and European cardiovascular cohort studies. *PLoS Med.* 2006;3(3):e44.

18. Bartlett C, Doyal L, Ebrahim S, et al. The causes and effects of sociodemographic exclusions from clinical trials. *Health Technol Assess.* 2005;9(38).

19. Nazroo JY. The structuring of ethnic inequalities in health: economic position, racial discrimination, and racism. *Am J Public Health.* 2003;93:277–284.

20. Wendler D, Kington R, Madans J, et al. Are racial and ethnic minorities less willing to participate in health research? *PLoS Med.* 2006;3(2):e19.

21. Hodge FS, Weinmann S, Roubideaux Y. Recruitment of American Indians and Alaska Natives into clinical trials. *Ann Epidemiol.* 2000;10(8, suppl):S41–S48.

22. Jones JH. The Tuskegee Syphilis Experiment. In: Emanuel EJ, Grady C, Crouch RA, Lie RK, Miller FG, Wendler D, eds. *The Oxford Textbook of Clinical Research Ethics.* Oxford, UK: Oxford University Press; 2008:86–96.

23. Hodge FS. No meaningful apology for American Indian unethical research abuses. *Ethics Behav.* 2012;22(6):431–444.

24. Samsudeen BS, Douglas A, Bhopal RS. Challenges in recruiting South Asians into prevention trials: health professional and community recruiters' perceptions on the PODOSA trial. *Public Health.* 2011;125(4):201–209.

25. Fisher JA, Kalbaugh CA. Challenging assumptions about minority participation in US clinical research. *Am J Public Health.* 2011;101(12):2217–2222.

26. Elliott C, Abadie R. Exploiting a research underclass in phase 1 clinical trials. *N Engl J Med.* 2008;358(22):2316–2317.

27. Ballantyne A. Benefits to research subjects in international trials: do they reduce exploitation or increase undue inducement? *Dev World Bioeth.* 2008;8(3):178–191.

28. Grady C. Money for research participation: does it jeopardize informed consent? *Am J Bioeth.* 2001;1(2):40–44.

29. Resnik DB. Research participation and financial inducements. *Am J Bioeth.* 2001;1(2):54–56.

30. Savulescu J. The Fiction of 'Undue Inducement': why researchers should be allowed to pay participants any amount of money for any reasonable research project. *Am J Bioeth.* 2001;1(2):1g–3g.

31. Australian Government: National Health and Medical Research Council. 2003. Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research. Available at: http://www.nhmrc.gov.au/guidelines/publications/e52. Accessed December 16, 2012.

32. Rogers W, Mackenzie C, Dodds S. Why bioethics needs a concept of vulnerability. *Int J Fem Approaches Bioeth.* 2012;5(2):11–38.

33. Lo B, Garan N. Research with Ethnic and Minority Populations. In: Emanuel EJ, Grady C, Crouch RA, Lie RK, Miller FG, Wendler D, eds. *The Oxford Textbook of*

Clinical Research Ethics. Oxford: Oxford University Press; 2008:423–430.

34. Warne D, Kaur J, Perdue D. Indian/Alaska Native cancer policy: systemic approaches to reducing cancer disparities. *J Cancer Educ*. 2012;27(suppl 1):S18–S23.

35. Motulsky AG. Frequency of sickling disorders in U.S. blacks. *N Engl J Med*. 1973;288:31–33.

36. Williams DR, Mohammed SA, Leavell J, Collins C. Race, socioeconomic status, and health: Complexities, ongoing challenges, and research opportunities. *Ann N Y Acad Sci*. 2010;1186:69–101.

37. Lantz PM, Lichtenstein RL, Pollack HA. Health policy approaches to population health: the limits of medicalization. *Health Aff (Millwood)*. 2007;26(5):1253–1257.

38. Wallerstein N, Duran B. Community-based participatory research contributions to intervention research: the intersection of science and practice to improve health equity. *Am J Public Health*. 2010;100(suppl 1):S40–S46.

39. Rothman RL, DeWalt DA, Malone R, et al. Influence of patient literacy on the effectiveness of a primary care-based diabetes disease management program. *JAMA*. 2004;292(14):1711–1716.

40. Kilbourne AM, Switzer G, Hyman K, Crowley-Matoka M, Fine MJ. Advancing health disparities research within the health care system: a conceptual framework. *Am J Public Health*. 2006;96(12):2113–2121.

41. Shamoo AE, Resnik DB. Strategies to minimize risks and exploitation in phase one trials on healthy subjects. *Am J Bioeth*. 2006;6(3):W1–13.

Research Ethics and Indigenous Communities

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Institutional review boards (IRBs) function to regulate research for the protection of human participants. We share lessons learned from the development of an intertribal IRB in the Rocky Mountain/Great Plains Tribal region of the United States.

We describe the process through which a consortium of Tribes collaboratively developed an intertribal board to promote community-level protection and participation in the research process. In addition, we examine the challenges of research regulation from a Tribal perspective and explore the future of Tribally regulated research that honors indigenous knowledge and promotes community accountability and transparency.

We offer recommendations for researchers, funding agencies, and Tribal communities to consider in the review and regulation of research. (*Am J Public Health*. 2013;103:2146–2152. doi:10.2105/AJPH.2013.301522)

RESEARCH ETHICS WITHIN

American Indian and Alaskan Native (AIAN) communities require a careful appreciation and respect for the areas of distinction and commonality that characterize appropriate use of scientific methodology within this sociocultural context. Conducting research in an ethical manner within indigenous communities necessitates an active awareness of the extent to which federal government agencies and affiliated institutions have oppressed, discriminated against, and engaged in culturally biased practices with these communities.[1] Examples include forced relocation of Native American people and punishment for their spiritual and cultural practices, forced removal of Native American children to boarding or residential schools, and in some cases direct warfare.[2,3]

The impact of these practices extends to the present-day health of indigenous people, who experience health disparities that stem from racism, loss of native language, loss of land, and complex socioeconomic factors.[4,5] Prior to their contact with European settlers, North American indigenous people had socioeconomic, spiritual, and linguistic structures that supported an indigenous worldview, that is, a perceptual understanding of the world based on holistic, cyclical, sacred, and spiritual connections.[6,7] However, European contact influenced indigenous people's worldviews, and Western European perspectives on science and reason have since ruled supreme. The Western scientific paradigm focuses on problems with solutions and dismisses any metaphysical explanations for reality.[8]

Colonization threatened the identity, culture, religious beliefs, and epistemological views of indigenous people[9] and led to the extinction of many Tribal nations that were vastly outnumbered and struggling with significant mortality associated with newly encountered infectious diseases. This diminished indigenous population faced a multitude of threats to its sovereign nation status, and Native American populations ironically became labeled as "minority" groups on their own homelands.[10] Contemporary AIAN populations represent about 2% of the US population[11] and are political entities with treaty rights and human rights to sovereignty; however, they continue to be classified simply as a minority group. Collectively they experience some of the nation's most severe and extreme health disparities[12] with respect to type 2 diabetes,[13] unintentional injuries, cardiovascular disease,[14] suicide and suicidal ideation,[15] homicide, and certain forms of cancer.[16,17]

Many Native American scholars and Tribes attribute the etiologies of these disparities to the sequelae of colonization that denied Tribal nations the right to continue their precontact life ways and indigenous science systems.[2,14,18,19] For example, the loss of Native American lands attributable to forced reservation relocation acts decreased the availability of traditional healthy diets and increased indigenous groups' consumption of unhealthy store-bought and commodity foods. Unhealthy diets, chronic stress, and decreased physical activity contribute to epidemic rates of obesity and type 2 diabetes in AIAN populations.[20]

Some have viewed research involving AIAN groups as an