

# AMERICAN ACADEMY OF PEDIATRICS

## POLICY STATEMENT

Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of All Children

Committee on Native American Child Health and Committee on Community Health Services

### Ethical Considerations in Research With Socially Identifiable Populations

**ABSTRACT.** Community-based research raises ethical issues not normally encountered in research conducted in academic settings. In particular, conventional risk-benefits assessments frequently fail to recognize harms that can occur in socially identifiable populations as a result of research participation. Furthermore, many such communities require more stringent measures of beneficence that must be applied directly to the participating communities. In this statement, the American Academy of Pediatrics sets forth recommendations for minimizing harms that may result from community-based research by emphasizing community involvement in the research process.

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ABBREVIATIONS. IRB, institutional review board; NARCH, Native American Research Centers for Health; IHS, Indian Health Service.

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The term “community-based research” is used to describe the conduct of research in community settings (in contrast to research conducted primarily in hospitals, clinics, or institutions specifically dedicated to medical research). Within the specialty of pediatrics, the Muscatine Study examining the natural history of childhood obesity in a small Iowa town is a well-known example.<sup>1</sup> Generally, such projects are embraced by communities because of the perception in European cultures that scientific enterprise is likely to yield information that is potentially beneficial. However, there are communities in North America in which cultural perceptions and historical experience create a different, somewhat hostile view of Western science and research. Such communities commonly comprise persons of ethnic minorities who may be economically disadvantaged, culturally isolated, or politically underrepresented. They may include people with strong ethnic/tribal affinity living in relative geographic isolation (eg, American Indian/Alaska Native individuals living on reservations) or immigrants of common national origin living within a specific urban neighborhood. Although institutional review boards (IRBs) have developed well-recognized procedures to minimize risk to individuals who participate in research studies, collective risks to members of specific geographic, racial, religious, or ethnic communities may

be overlooked. The purpose of this statement is to outline the special research-related concerns of such communities and to suggest means by which investigators working with socially identifiable communities can minimize risks and maximize benefits involved with research. The considerations discussed apply to the broad spectrum of research pursuits that may take place in such communities.

#### SPECIAL RISKS TO SOCIALLY IDENTIFIABLE POPULATIONS

Risks to socially identifiable populations or communities generally can be subdivided into 2 areas: external risks and intracommunity risks. Although most researchers and IRB members have some familiarity with the former, the latter are seldom understood or regarded outside the community of interest.<sup>2</sup>

##### External Risks

Harms inflicted by outsiders are the best-known collective risk to people with a shared social or cultural identity. Racism, with all its negative components, is an obvious example of this sort of external risk. However, investigators seldom appreciate that the research enterprise may have unintended harms on the ethnic, religious, and social well-being of isolated or socially identifiable communities. These unintended harms may affect economic, social, legal, and political life within such communities.

##### Economic Risks

The lay press and professional journals have given considerable attention to the potential for employment and insurance discrimination on the basis of genetic information uncovered in the course of genetic research studies. Theoretically, individual research participants and their communities may be placed at risk by such activities. Although few cases of genetic discrimination have been documented, it continues to be a major concern.<sup>3</sup> The same can be said for other kinds of community-based research. For example, documentation of a high prevalence of human immunodeficiency virus infection or domestic violence within a community could have important adverse economic effects on that community, ranging from increased insurance rates for commu-

nity members to decisions by businesses to move into or remain in that community.<sup>4</sup>

### Social Risks

Studies that focus on community problems (eg, drug abuse, human immunodeficiency virus infection, teen pregnancy, youth violence) run the risk of stigmatizing such communities or inadvertently reinforcing common misconceptions about such communities within the dominant culture. Community members also may be harmed by the way they see themselves or one another in light of data that emphasize negative aspects of community life and neglect positive aspects of the community or culture. In each case, these harms may disproportionately affect children, whose cultural identity and self-esteem may be closely linked. Genetic studies inadvertently may limit community members in their opportunities for social interactions including marriage, adoption efforts, and child-custody claims.

### Legal and Political Risks

In the United States, American Indian and Alaska Native persons share special social and political status on the basis of their descent from the people who inhabited the land before European contact. Issues of tremendous social, political, and economic complexity may be raised by research (including but not limited to genetic studies) that challenges claims of descent or status as original inhabitants of a specific region (eg, the “Kennewick Man” discovered in Washington state<sup>5</sup>). Thus, research findings or interpretations that might be innocuous to some communities may threaten the existence of others.

### Intracommunity Risks

As noted previously, intracommunity risks may not be considered when IRBs review research involving human subjects, in part because intracommunity harms are highly localized and often not evident to those outside the community. Nonetheless, outside involvement in local communities—even seemingly beneficial interventions—can be highly disruptive to existing social relationships. Although the involvement of local community members on university IRBs, encouraged by federal regulation, may reduce the occurrence of such harms, it is unusual for communities geographically removed from university centers to have representation on university IRBs. Perhaps the most important consideration from the point of view of socially identifiable communities is the risk to cultural and moral authority that may be engendered by community members’ participation in research.

Although informed consent by individuals participating in research is the standard by which many Europeans and Americans judge the ethical propriety of research activities, many societies require collective consensus and assent. Such considerations were, for example, at the heart of the establishment of the Iroquois Confederacy more than 500 years ago.<sup>6</sup> Collective assent is especially important when research activities or findings may affect the whole community. IRB standards and procedures that gov-

ern the protection of human subjects in scientific research are based on the rights of individuals. Research cannot be conducted without the informed consent of individuals (or in the case of children, the consent of their parents). However, in many instances of community research, there are other ethical considerations of collective consensus and assent that should be carefully considered and, where appropriate, documented. For example, the University of Washington’s IRB requires documentation that appropriate letters of tribal support be presented for research projects involving American Indian/Alaska Native communities. Area offices of the Indian Health Service (IHS), which also sponsor IRBs for research conducted in their areas, maintain the same requirement.

None of these considerations should be construed to indicate that community consent may properly override the autonomy of an individual who does not wish to participate in research.

Involving community members and groups on the research team from planning, through analysis, and to dissemination of the results will help the research team recognize potential risks to the community and identify how best to avoid or minimize them.<sup>7</sup>

### SPECIAL POTENTIAL BENEFITS TO SOCIALLY IDENTIFIABLE POPULATIONS

In addition to having to consider unique aspects of informed consent in socially recognizable communities, many indigenous populations desire a rethinking of the concept of beneficence, that is, of doing no harm while maximizing potential benefits.<sup>8</sup> In conventional views of research, an acceptable understanding of beneficence includes the notion that, although the research may not directly benefit study participants, it has significant potential to benefit society as a whole or to benefit some portion of the society (eg, people with a specific disease). Many indigenous populations have expressed dissatisfaction with this interpretation of beneficence and have required, instead, that research proposals contain concrete, well-defined plans for how the research findings will be used to directly benefit the community.<sup>9</sup> In many instances, such requirements include involvement by researchers in the community even after the data-gathering phase of the research is complete. Thus, for example, a study examining the impact of violence in a neighborhood’s public schools might be considered unacceptable if the investigators proposing the study could not articulate clearly how study results might be used to ameliorate the problem.

The early and continuing involvement of community members and groups on the research team will help the team recognize potential benefits to the community and identify how best to maximize them.<sup>7</sup> The medical and public health literature contains numerous examples of successful research partnerships established between academic organizations and socially identifiable communities. The Kahnawake Schools Diabetes Prevention Project in a Mohawk community in Canada is an excellent example of the mutual benefits researchers and commu-

nities derive from ethically sound community-based research.<sup>7</sup> Successful research projects have been undertaken with community participation from the onset of the project, including writing the research proposal and grant application.<sup>10</sup> The establishment of community members as principal investigators in research projects was given further strength and credibility by the recently combined IHS/National Institutes of Health program for establishing Native American Research Centers for Health (NARCH). The NARCH initiative, which partners American Indian and Alaska Native tribes with academic centers and other research institutions, identifies tribes as the investigators and research institutions as partners, a direct reversal of what has been common practice until now. The National Institutes of Health-funded Excellence in Partnerships for Community Outreach, Research on Health Disparities and Training (Project EXPORT) encourages the same approach with other minority communities. The NARCH and Project EXPORT initiatives have the potential to promote the benefits of national, multisite research partnerships between academia and communities and to further the impact of community-based, socially responsible research.

In summary, the ethical conduct of research in socially identifiable communities requires application of standards not commonly used in biomedical or social sciences research. These special considerations are based on the cultural views of many such communities, their historical experience with European-dominated cultures, and in many cases, the unique political statuses of these communities. Important elements of the responsible conduct of research in and with such communities include engaging indigenous or other socially identifiable communities as partners in the research enterprise, developing common goals for researchers and community members, recognizing potential risks and identifying how best to avoid or minimize them, recognizing potential benefits and identifying how to maximize and achieve them, and using knowledge gained from the research to assist communities in need. Investigators who are meticulous in observing these standards almost invariably find that their research goals are met while they are enriched by a deeper knowledge of the unique histories and cultures of their community partners.

### CONSIDERATIONS

In addition to the aforementioned points, the following concepts should be considered by researchers seeking to engage socially identifiable communities in research activities.

1. Members of the research team and, where appropriate, research sponsors should strive to assist community organizations in the designing and implementing of interventions based on their research findings. If, for example, the project has examined the prevalence of hypertension among obese adolescents in an inner-city community, researchers should be encouraged to follow their

study with concrete assistance to the community in addressing this problem.

2. Efforts should be made to include persons of ethnic minorities as researchers on these teams. Given the small proportion of researchers of ethnic minorities, it is critical that mentorship opportunities be created for these individuals.
3. Researchers should offer their expertise to individuals in the community who may want to develop their own research to address questions raised by the original study.
4. Individual researchers are supported by academic institutions that also have responsibilities to communities. Institutions are strongly urged to create and maintain educational, training, and funding opportunities that facilitate the mentoring relationships necessary to enable communities to cultivate researchers, particularly those of ethnic minorities.

### RECOMMENDATIONS

Several steps can be taken during the planning phase of a community-based research project to minimize the aforementioned risks.<sup>11,12</sup> It should be noted that these recommendations may not be applicable to every community. Communities sharing identical views as the dominant culture (eg, a project conducted in a neighborhood in suburban Boston) may not require the same cautious and painstaking approach. Thus, "community" here will refer to socially identifiable groups (not necessarily living in the same geographic region) for which there is a reasonable possibility that group ethos concerning research and/or community responsibility may differ from the dominant culture.

1. Members of the community should be consulted in the planning of the research and the definition of research objectives. Potential benefits to the community should be articulated clearly and unambiguously.<sup>13</sup>
2. Research participants should be considered partners, not research subjects. Responsible members of the community (eg, tribal health care leaders, planners) should have ongoing oversight of the project and be given responsibility for ensuring adherence to the original goals of the project and procedures designed to protect the community. (Research that expects to use any resources of the IHS [eg, IHS personnel, review charts, blood work] must first comply with the IHS requirement that the tribal government explicitly approve the research.)
3. Community members should be the first to be informed of study results. They should be active participants in the analysis and interpretation of data. To provide community members the opportunity to articulate their interpretation of study findings, community members also should be consulted about proper methods for publishing and disseminating the data gathered in their community.
4. If there is potential that the results could be damaging to a specific community, research investiga-

- tors should keep the community anonymous when publishing and presenting the results.
5. Human research protection programs and IRBs should utilize appropriate options provided within the federal regulations (45 CFR 46) to guarantee that proper representation of community interests is part of the ethical review process. This often will require the recruitment of experts from outside of the IRB to help in the review of community-based studies. Appropriate IRB review of community-based research should also be promoted and enforced within human research protection accreditation standards.

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