THE PROTECTION OF POTENTIAL INDIVIDUAL VOLUNTEERS AND TRIBAL COMMUNITIES IN RESEARCH INVOLVING THE INDIAN HEALTH SERVICE (IHS)

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U.S. Congressional law is the basis for federal health services to American Indian and Alaska Native (AI/AN) people. The Indian Health Service (IHS) of the Public Health Service has primary responsibility for those services. The IHS goal is to raise the health status of AI/ANs to the highest possible level. Its mission is to ensure equity, availability, and accessibility of a high quality comprehensive health care system. Its mission also is to maximize the involvement of AI/ANs in defining their health needs, setting health priorities for their local areas, and managing and controlling health programs. Tribes can and do manage the programs in their communities under Public Law 93-638, Indian Self-Determination Act of 1975. Tribes also can and do take over their entire federally-funded health programs under the process of Self-Governance.

IHS has 12 Area (regional) offices. IHS provides and supports a broad set of preventive, curative, rehabilitative, and environmental services. As of October 1998, Tribes operated 85 local administrative “Service Units,” 12 hospitals, 155 health centers, 3 school health centers, 76 health stations, and 160 Alaska village clinics. IHS operated 66 Service Units, 37 hospitals, 59 health centers, 4 school health centers, and 44 health stations. More than 1 million members of AI/AN tribes received services in those facilities in 1998.

Much research is done in AI/AN communities by outsiders such as universities, by Tribes and IHS Service Units, and by the IHS Research Program. Institutional Review Boards (IRBs) help ensure that all research observes three principles of ethics: (1) respect for persons; (2) beneficence (to do no harm, and to maximize benefit); and, (3) Justice. IRBs look closely at the negotiation between researcher and each potential volunteer, called the “informed consent process.” Due to concern about Tribal sovereignty and self-determination, the IHS IRBs look both at the negotiation between researcher and *each potential volunteer*, and also that between researcher and *the tribal community*. That is, IHS IRBs help ensure that all research observes the same principles – respect for persons, beneficence, and justice – applied to the AI/AN communities.

The following table shows how those three ethical principles in research apply to individual volunteers and to AI/AN tribal communities.

Ethical Principles	Individual Person	Tribal Community
Respect for Person and Respect for Tribal Community	• People are autonomous; researchers must give them required information and obtain their fully informed consent • The research does only what the person consents to. For instance, people are not identified in results without their explicit consent; they can refuse or withdraw their participation without	• Tribal communities are autonomous; researchers must give them required information and obtain their fully informed consent • The research does only what the Tribe consents to. For instance, Tribal communities are not identified in results without their explicit consent; they can refuse or withdraw

	pressure • Special people have special concerns. For instance, IRBs should include members with expertise about such concerns.	their participation without pressure • Tribal communites have special concerns. For instance, IRBs should include Tribal members with expertise about community concerns.
Beneficence	• Maximize benefits to individual volunteers. For instance, report their findings to them. • Minimize risks to individuals. For instance, protect their privacy to avoid being stigmatized	• Maximize benefits to tribal communities. For instance, report research results to them; researchers and Tribes plan research together. • Minimize risks to tribal communities. For instance, protect their privacy to avoid being stigmatized
Justice	• People with less power should not be asked to undergo risky research that is of little benefit to them • People with less power should be included in potentially beneficial research	• Tribal communities should not be asked to permit risky research that is of little benefit to their members or themselves • Tribal communities should be included in potentially beneficial research

IHS has 12 IRBs, one for each Area and a Headquarters IHS IRB that also covers the Albuquerque Area. The Navajo Nation has its own IRB, whose members the IHS also appointed to its Navajo Area IRB.

The IHS IRBs use the ideas outlined in the table to ensure protection not only of the individual volunteers in research, but also of the tribal communities in which the research takes place. The IHS is committed to the self-determination and cultural integrity of AI/AN communities. Three IHS policies reflect that commitment:

- By Federal regulations 45 CRF 46, every IRB must have at least one member whose primary interest is "non-scientific." In the IHS IRBs, the "non-scientific" members must be enrolled members of tribal communities. In most IHS Area IRBs, the proportion of members who are AI/AN is close to or exceeds 50%.
- All research and resulting publications must be approved by the governments of the tribal communities involved in the research
- IHS IRBs encourage researchers to give, and tribes ask for, a required set of elements of information (similar to the required set of elements in 45 CFR 46 for individual volunteers' consent), to ensure that the tribes' consent is truly informed.