

Compilation on Environmental Health

Research Ethics Issues with Native Communities

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Compilation of Environmental Health Research Ethics with Native Communities

I. Introduction

This document includes a collective summary of research ethics issues in the conduct of research with Native American/other indigenous populations. Although the focus of this effort is environmental health, research ethics issues from other health initiatives are included to compensate for the paucity of literature in the environmental health field. The findings from these other health-related fields are directly applicable to environmental health. The data has been drawn from fourteen articles and case studies in the literature that specifically focus on research ethics with Native communities and participatory research strategies. Case studies are drawn from United States, Canada and Australia. The types of research investigations range from diabetes, cancer screening, other medical interventions, to environmental health topics of management of nuclear risks and toxic contamination risks.

There were not that many case studies of participatory research with Native Americans on health-related issues. One positive outcome of this summary would be to assist in promoting more such studies with this research paradigm in Native communities. A focus on the impact and outcomes of participatory research case studies is included to evaluate how the desired goals of these studies were actually achieved. The successes and challenges of these studies will likely be informative for other investigators and community members. More complex issues addressed by this report include informed consent, ownership of research data, disclosure of results and guidelines for dissemination of research findings. Not all authors are in agreement with each other and this is indicative of the unique problems of differing contexts and research arrangements.

In the presentation of this information, one can see the important contributions and benefits of involving community members in equitable research practices. Many scientists may see community partnership arrangements as cumbersome and stifling to their work. Traditional scientific research has excluded community members from the research process, leading to flawed research. As such, important knowledge that could have been gained about environmental health impacts was lost. More importantly, research that was not responsive to community needs resulted in further harm to communities already burdened by the severe problems of environmental contamination. This compilation was put together to assist future research partnerships in achieving successful outcomes from their investment of time and resources.

II. Case Studies and Selected Articles

The following case studies and reports are included in this document for the compilation of research ethics issues.

1. Akwesasne Research Advisory Committee,, “Akwesasne Good Mind Research Protocol.”, Akwesasne Notes, v. 2, No. 1, Winter 1996
2. Lyons, Oren, “Ethics and Spiritual Values and the Promotion of Environmentally Sustainable Development” Akwesasne Notes v. 2, No. 1, Winter 1996:88
3. Beauvais, Fred; “Obtaining Consent and Other Ethical Issues in the Conduct of Research in American Indian communities”, *Drugs and Society* v. 14, i.1-2, p. 167, Winter-Summer 1999
4. Davis, Sally; Reid, R. “Practicing Participatory Research in American Indian Communities”, *American Journal of Clinical Nutrition*,v.69, i4, p.755s(1), April 1999
5. Foster, MW; Bernstein, D; Carter, TH;; “A model agreement for genetic research in socially identifiable populations.” *American Journal of Human Genetics*. Sep. 63 (3) : 696-702, Sep, 1998
6. Foster, MW; Sharp, RR, Freeman, WL; Chino, M; Bernstein, D; Carter, TH;; “The role of community review in evaluating the risks of human genetic variation research”; *American Journal of Human Genetics*. June. 64 (6) : 1719-27, Sep, 1999
7. Herbert, CP; “Community-based research as a tool for empowerment: The Haida Gwaii Diabetes Project example.” *Canada Journal of Public Health* 87 (2): pp. 109-12; Mar-April 1996.
8. Indigenous Peoples Council on Biocolonialism, “Indigenous Research Protection Act”, email ipcb@ipcb.org, 2000
9. Lyons, Oren; “World Bank, October 3, 1995, Ethics and Spiritual Values and the Promotion of Environmental Sustainable Development ’50 Years of the World Bank, Over 50 Tribes Devastated””, *Akwesasne Notes*, Vol 2, Number 1, 1998.
10. Maddocks, Ian; “Ethics in Aboriginal Research; a model for minorities or for all?”, *The Medical Journal of Australia*, v. 157, October 19, 1992.
11. Macaulay, Ann, “Ethics of Research in Native Communities”, *Canadian Family Physician*, v. 40, November 1994.
12. Matsunaga, DS, Enos, R., Gotay, C., Banner, R., DeCambra, H., Hammond, O., Hedlund, N., Iiaban, E., Issell, B., Tsark, JA, “Participatory Research In a Native Hawaiian Community”, *Cancer*, v.781,1996
13. Montour, Louis T. and Ann Macaulay, “Diabetes Mellitus and Atherosclerosis: Returning Research Results to the Mohawk Community”, *CMAJ*, V. 139, August 1, 1988
14. Norton, I. and Manson, S., “Research in American Indian and Alaskan Native Communities: Navigating the Cultural Universe of Values and Process”, *Journal of Consulting and Clinical Psychology*, v.64, No.5, 1996
15. Quigley, D.; Sanchez, V; Goble, R.; Handy, D; George, P; “Participatory Research Strategies for Nuclear Risk Management for Native Communities” *Journal of Health Communications*, Vol. 5, No. 4, pp.305-333. Oct-Dec. 2000
16. Scott, Kim and Receveur, Olivier, “Ethics for Working with Communities of Indigenous Peoples”, *Canadian Journal of Pharmacology* 73:751-753, 1995

III. Historical Context of Academic Research in Native American Communities

Many of the authors of these case studies introduce their articles with a justification for adopting partnership guidelines with indigenous communities. These justifications include statements about the abuse and exploitation of these communities by academic researchers in the past.

Ian Maddocks (1992) writes that “Some part of the anger which Aboriginal Australians express with increasing clarity centres on their interpretation of many past scientific expeditions and surveys studying Aboriginal people. These studies were seen as insensitive, intrusive, exploitative, and conferring no benefit on the communities at all” Maddocks describes how uncomfortable scientists are in the face of such charges as they see themselves as liberal, objective, upholding a view of science as value-free, fearlessly adding to the sum of human knowledge. In the body of his recommended guidelines, he warns against such practices as scientists recruiting individuals in communities for opportunistic reasons; violating the group solidarity of the community.

Maddocks states that some scientists are worried about the types of partnership arrangements and guidelines that are being instituted. These scientists see that these guidelines have the potential to prevent the pursuit of important scientific questions or to stop the publication of scientific findings; stopping the free-flow exchange of information, which is the life-blood of science. Maddocks highlights that ethical research practices will ensure the participation of the Aboriginal communities in research. That participation is more critical. Ethical research will also bring more benefits to the community and perhaps attract Aboriginal graduates to research and science. He closes with this quote by an Aboriginal community member “White-dominated science will benefit greatly by abandoning its role of “wise big brother” and by awaiting for Aborigines themselves to define the questions that are important to them and to employ science as a liberating and empowering force for Aboriginal welfare.”

The Akwesasne Research Advisory Committee (1996) reported that Akwesasne has been a hot spot for environmental research due to the advent of the Superfund Cleanup. Many university institutions thrived on environmental research there and external agencies conducting research were swamping Akwesasne with projects already approved and funded. For the most part, this research was overlapping and not benefiting the real needs of the community. Montour and Macaulay (1988) wrote that “only rarely do researchers live or work in aboriginal communities. Aboriginal groups are naturally wary when outsiders want to do ‘studies’. Outside research teams swoop down from the skies, swarm into town, ask nosy questions that are none of their business and then disappear, never to be heard from again.” The biggest complaint that Montour and Macaulay heard from community members is that they never get any feedback from studies performed on them.

Herbert ‘s (1996) article raised the same issue. Community health representatives (CHRs) complained that the community perceives researchers as parachuting in, taking samples of blood, hair or other body substances, then disappearing with nothing of value resulting to the community. The CHRs also cautioned against research that raises difficult health issues for the community that they would be left to deal with on their own after the project is completed. The researchers are gone and there are no resources available to deal with the

issues. Similarly in Matsunaga et al.'s article on "Participatory research in a Native Hawaiian Community", they state that health promotion programs for Native Hawaiians have failed mostly due to the cultural inappropriateness of traditional research models. The principle planners and decision-makers were university-based researchers who left Native Hawaiians feeling exploited and used as 'guinea pigs.' These authors found that participatory research models were far more culturally appropriate and produced many positive outcomes.

Beauvais (1999) writes that due to the explosion of knowledge in the physical sciences throughout this century, researchers have been afforded some degree of latitude regarding the impact of the knowledge they generate. However, great debates have also arisen as to whether or not the pursuit of "knowledge for its own sake" without the regard for consequences is morally justifiable." Beauvais reiterates the point that information can be gathered by social scientists, used or perceived in such a way that is detrimental to the community or the individuals within it. Research benefits exclusively those who conduct the research with no benefit to the community and sometimes has a potential negative impact on the community of study. This exploitation of research participants is most common in minority communities. He cites an egregious example of this in an Alaskan Native community.

Davis and Reid (1999) comment on the unconsciousness on the part of scientific researchers who focus on goals of benefiting humanity, expanding scientific knowledge and advancing their careers, without being aware of the potential exploitation of their research subjects. Some harmful consequences of research to Native communities included an epidemiological study that a state health department conducted of an outbreak of syphilis on an Indian reservation. After local newspapers published the findings, the neighboring non-Indian population ostracized both Indian adults and children from that reservation. A later scientific article neglected to mask the community's identity sufficiently enough, resulting in a sense of betrayal among the participants of the study. Identifying a Native community in a study of alcoholism led to an adverse credit rating for that community with lenders. Publications about the hantavirus in 1993-94 listed the Dine (Navajo) sites involved when it was requested that this not be included. Repeated violations of trust by researchers have justifiably soured American Indian interest in participating in research. Few non-native researchers possess an awareness of American Indian culture and belief systems; researchers have little awareness of the ethnohistorical context of the relationship between Native and non-native people; or the continuing effect of American colonialism on the peoples they seek to study.

As tribes have asserted their rights of sovereignty and established laws, policies and regulations for outside researchers working on their reservations, researchers have begun to respond within increased awareness and sensitivity to Native people. These authors seek to develop more cultural sensitivity on the part of researchers by discussing historical issues that affect research in Indian communities; how these issues relate to culturally-sensitive, respectful research and by promoting participatory research as a viable paradigm for the future.

Environmental Health Research Injustices

The Quigley et al.(2000) article elaborates on a number of research abuses in the field of environmental health. They identify concerns such as "reductionist science 'which relies heavily on hypothetical quantitative models to determine disease excesses in communities with environmental contamination, while community knowledge about health impacts and environmental abnormalities is excluded. Community members are not included in scientific decision-making bodies that set standards of exposure and risk to community members. Other

research injustices cited were (1) the contracting of politically-biased research teams which would exonerate polluting facilities; (2) inadequate contact with the populations being studied by researchers (3) inappropriate statistical methods for small and mobile populations around waste sites (4) studying the wrong types of health outcomes (certain illnesses or cancers) and not including health outcomes of concern to community members.

Research injustices specifically related to the tribes near the Nevada Test Site (NTS) include a lack of research of the exposures to Native populations. The tribes were omitted in a government study of off-site exposures to the local populations residing near the NTS due to inappropriate outreach methods. After being exposed to over 900 above and below-ground nuclear tests in the 1950's and 1960's, no health studies had ever been performed to understand the impact of these exposures on the tribes. The tribes instead were deceived by government scientists who consistently assured them that the exposures they received were safe. Environmental health research methods also do not take into account special risks to Native populations from radiation exposures. These methods are usually designed for mainstream non-native populations. A list of these additional injustices was included in this article from a correspondence with a Native community leader.

- Native community members and leaders are lied to about what their participation meant in certain settings; they were not given training or preparation for their role and purpose in providing input; they were intentionally confused so external control could be maintained.
- Native input often is appropriated by non-Native people without permission, acknowledgement or recognition of Native contributors or Native culture.
- Involvement of Native representatives has not reflected the diversity of tribal communities and interests in public participation forums.
- Native community members and leaders were notified too late or excluded from input into major environmental decisions affecting their communities.”

Research Injustices in Human Gene Studies and Native Communities

The Human Genome Diversity Project, a project of the World Bank, has been a highly controversial research activity in Native communities. Oren Lyons, a Native writer and university professor, published an article in *Akwesasne Notes* (1996) questioning the ethics of this project that seeks to preserve the DNA cell lines of indigenous populations around the world. Lyons questions why indigenous people were not invited into any of the planning processes for this project which were funded by the National Science Foundation. Indigenous values and perspectives were excluded from the dialogue while Anglo-European values and priorities dominated the process. He states that indigenous peoples did not ask for their cells to be preserved. He questions what the impacts will be of allowing corporations and individuals to patent the genes of indigenous peoples. Lyons fears that this will just be another harmful development project of the World Bank that will victimize indigenous peoples. In response to these concerns, an Indigenous project was formed, “The Indigenous Peoples Council on Biocolonialism” which has developed an Indigenous Research Protection Act.

Foster et al. have carried out several exploratory research initiatives in Native communities for establishing community review and model agreements for the conduct of genetic research. He too highlights various historical ethical problems in genetic research in these studies. Currently it is common practice to name ethnically, geographically and linguistically identifiable populations in public data-bases and scientific publications. That practice however may entail collective risks for all members of that population and not just for those who participate in the study. The primary risk is that of laypersons who may misuse scientific

findings: e.g. hereditary to support racism and other discrimination. Prominent examples include associations of African-Americans with sickle-cell trait and Ashkenazi Jews with specific BRCA1 alleles. The Human Genome Project recognizes that members of a socially identified population may be adversely affected if associated with a genetic predisposition. Other risks include the contradiction of population's sense of its own history, broader forms of discrimination and stigmatization, internalized social stress or the disruption of a community's social equilibrium.

There is emerging bioethics literature that has begun to raise questions about collective issues: What research ethics are appropriate in culturally diverse situations? How can researchers minimize the risks of stigmatizing entire categories of people? How can individual privacy be protected in small populations. Who should profit from valuable information derived from a unique population? Under what conditions can DNA be collected for one project later be used for other research. There is much variation among diverse cultural and ethnic identities in how they decide to participate in research studies or make treatment choices. Researchers should be aware of the possibility of unintentionally imposing a foreign social structure on members of other cultures.

Foster cites several studies of researchers who are opposed to giving special consideration to the interests of socially-identifiable groups. They state that such consideration is paternalistic and inherently demeaning. Some researchers deny that collective risks actually exist; that these are undocumented and intangible fears. Foster and his colleagues put forward some important guidelines for developing community review processes and working with Native communities in a constructive collaborative process.

III. Guidelines/Recommendations for Partnerships and Collaborations for Researchers and Native Community Members

Each of these articles has set out either principles for conducting collaborative research or recommendations for doing so. To capture all these principles and guidelines, a collective list has been compiled from a synthesis of the articles. This list is included below and will provide a structure for reporting on the recommendations and guidelines of the articles. After highlighting these injustices, the authors of these case studies present alternative research models with the identification and discussion of more ethical research interventions. Of particular importance is the trend toward partnership or participatory research between external researchers and Native community members. This section provides a summary of guidelines and excerpts from articles on developing partnership arrangements and collaborative agreements with Native communities in the conduct of research investigations. Twelve key recommendations are listed with a discussion of how the various authors have encouraged or implemented these recommendations in their work.

A. Collective List of Research Ethics Guidelines and Recommendations:

- (1) Preparing for Research in a Native Community
- (2) Developing the Collaboration or Partnership – Community Advisory Committees
- (3) Initial Administrative Arrangements between Researchers and Community Members
- (4) Community Education on Risks and Benefits of the Research Proposed
- (5) Representation/Involvement of Community Members in All Stages of Research Process

- (6) Equity – Reimbursement or Incentives for the Community or Involving the Community in the Research Execution
- (7) Local Knowledge Validation, Incorporation of Native Perspectives in the Research Questions
- (8) Cultural Sensitivity Training
- (9) Informed Consent Issues – Autonomy, Confidentiality, Voluntariness
- (10) Data Control and Ownership, Interpretation, Dissemination, Publication
- (11) Longevity and Follow-up
- (12) Impact and Empowerment

Each of these themes are dealt in detail in the following pages:

(1.) Preparing for Research in a Native Community

Several authors of these case studies discussed a certain amount of preparation that should be carried out before seeking cooperation from Native communities in research proposals. These activities should assist the researcher in determining whether the researchers' goals and the community needs are compatible.

Davis and Reid discuss the importance of preparation in terms of understanding cultural contexts. They note that many American Indians feel that researchers do not recognize the rich diversity of tribal heritages that remain vital today or the uniqueness of the tribe with which they work. Elements of cultural context that they emphasize include:

- (a.) *Understanding Cosmologies* - Researchers should familiarize themselves with the cosmologies of the tribes they are working with. The authors elaborate on key beliefs of other life forms being as brothers and sisters; the land is not separate from humans; the American Indians adhere to their religious beliefs with an intensity that is incomprehensible to researchers. Religion plays no role in the research of most scientists. This becomes an issue when researchers do not put a value on the sacredness of blood when seeking blood or bodily fluids.
- (b.) *Sacred and Secular Information* - Thought and word hold a great importance in American Indian society as a means of cultural survival. As they work with American Indians, researchers should be aware that some information that they believe is secular in the dominant society could compromise sacred knowledge in American Indian cultures. English, the language of science and research in the U.S., fails as a communication tool to explain native cosmologies. Native speakers in the research process become critical in fostering clear communication and overcoming barriers associated with language.
- (c.) *Fear of Condescension and Exploitation* - Traditional research approaches are frequently invasive to American Indians. Condescending researchers, who are the principal planners and decision-makers of the project, can make American Indians feel that they are being reduced to objects. Community response to feelings of exploitation in the research process may result in either indirect resistance or direct sabotage.
- (d.) *Recommendations*: The authors conclude with these recommendations:
 - Before approaching Indian communities, researchers should determine the benefit to the community of the research; and they should learn and understand the religion, beliefs and culture of the people they wish to study to ensure compatibility with their goals.
 - During negotiations with American Indian communities, community representatives should be involved in the development and execution of the research efforts. Different philosophies of time and decision-making need to be respected. Indian time is cyclical-linked to myth and memory. Decisions often require consensus instead of majority rule.

- During and after the research, feedback sessions should be scheduled with the community to ensure correct collection and interpretation of the data and project evaluation. American Indian professionals in the field of study should be invited to participate in peer review. Lastly, researchers should establish with community representatives a value exchange of their time (skills, training, employment, training access to funding, and mentoring).

Beauvais (1999) states that conducting good applied research requires a thorough knowledge of the populations that are involved in the research. He highlights a list of contextual conditions to be considered in both the design and feasibility of conducting good research. Beauvais warns that research designs that do not take into account the realities and the culture of the population under consideration will only yield uninterpretable results. Many research projects fail because too little effort is expended in the early part of the process in getting acquainted with the community and understanding its history, politics and culture.

- *Tribal Sovereignty* – Tribes differ from states in their relationship to the federal government; tribes have much greater authority than states in regulating their own affairs. Tribes are not subject to the laws and regulations of states where their reservations exist. Tribes feel that the terms and conditions of the conduct of research, including consent procedures should be under tribal control and balk at regulations that they believe are inappropriate for their circumstances. However, federal regulations often accompany federally funded research projects. *Differences between tribal expectations and federal requirements must often be negotiated before the research can take place.*
- *Infrastructure*: The educational, social and health service infrastructure of many tribal communities is often underdeveloped. Routine demands are often difficult to accommodate. Reservations are in remote areas where the physical infrastructure makes life difficult (roads and communications). Reasonable research demands often cannot be met easily. Transportation arrangements and/or reimbursement must be anticipated in the research plan and may add considerable cost to the project.
- *Wariness*: Tribes are organizing research committees to overcome past research exploitation (duplicity, Indians used for research data while many of their disadvantaged conditions are not ameliorated). These committees ensure that the research has benefit to the tribe and does not exploit the community or individuals. It is incumbent upon the researcher to fully inform these committees of the nature of the research and to negotiate a mutually acceptable research plan.
- *Multiple Layers of Approval*: There are often multiple layers of bureaucracy involved in Indian reservations. The author indicates that if a research project requires human subject's approval, there could be at least 14 agencies that might need to be involved in one way or another.
- *Urgent Need for Data*: Often tribes do not have the luxury of time in their need for data. Various negotiations and arrangements to be made for consent data could preclude the timely collection of data. These conflicting needs often need to be weighed and negotiated.

(2.) Developing the Collaboration and/or Partnership - Community-based Research Committees

Most of the attached case studies stress the importance of a community advisory committee in developing community-researcher partnerships. The following summary will include some descriptions of this collaborative mechanism as reported by the authors.

The Need for the Community Advisory Committee

Maddocks states that the first requirement of consultation is to discuss the research aims with an aboriginal ethics committee. The committee can provide input on the feasibility, the methodology, and acceptability by the community. With the committee, the researcher can determine the benefit of the research to the community and be educated on cultural sensitivity issues.

Macaulay et al. make an important distinction in organizing partnerships. “ In partnerships, the organizing principle is the location of the project leadership: when the community group is the senior partner, projects are designed and implemented by the community and the academic partner is contracted to assist with particular problems. When the senior partner is the academic partner, authority begins with them and gradually transferred to community groups. Programs with balanced partnerships occur when the leadership shifts back and forth, depending on which group has expertise for a given problem”.

Additionally, the authors state that the community to be studied should be represented in the ethical review process. It should not be considered that lack of education disqualifies community members from joining in constructive discussion on issues relating to the study and application of the findings. Researchers and project staff first review existing codes of ethics and recommendations for research with Native communities. In the Macaulay et al. research effort, the Native Mohawk community of Kahnawake had a community advisory board (CAB) consisting of 40 volunteers. The CAB reviewed codes of research ethics and their comments were incorporated. This process took eight months but the authors commented that it was well worth the time it took in order to secure the community’s cooperation with the research.

The Akwesasne Task Force on the Environment developed a Research Advisory Committee for the burgeoning number of research initiatives being proposed for their community. Specifically the ATFE’s RAC seeks to protect the community from the potential exploitation of researchers. They have defined the purpose of their committee as follows:

The Purpose of the Research Advisory Committee – The RAC is guided by several key principles: Skennen (peace), Kariwio (good mind) and Kasastensera (strength) as related to the community by oral tradition from their ancestors. Peace is the striving for universal justice; good mind is stressed as “the shared ideology of the people using their purest and most unselfish minds and strength; the power of the good mind to use rational thinking and persuasion to channel the good will of humans to work toward peace, justice and unity to prevent the abuse of human beings and mother earth.” Within this context, the overall purpose of the RAC is to review and comment on all scientific and/or environmental research proposals to be conducted in the Mohawk Nation community of Akwesasne. The RAC was given authority to do this by the community. This will ensure the establishment of a good research agreement that is both culturally sensitive and relevant to the participant and the community. A minimum of five people serves on the committee and the ATFE as a whole decides the merit of the proposal.

Quigley et al. stressed the development of a community advisory as their first goal with the community. The university subcontracted a portion of the research budget to a community organization (Citizen Alert Native American Program), staff of CANAP served as co-principal investigator and community researchers. The CANAP co-principal investigator then recruited an eighteen-member advisory committee. As the research effort was for tribes affected by nuclear fallout downwind from the Nevada Test Site, the committee represented nine tribes from Nevada, Southern California, and Utah. Representatives included those tribal

members who were active in environmental organizing, representatives from local tribal councils and elders who held much local knowledge.

The formation and ongoing implementation of meetings for the committee was a significant portion of the community budget to accommodate this representation but it was a critical mechanism for community partnership, collaboration and empowerment. The authors report that it was the first satisfying experience of public participation that the tribes had with external researchers. Eventually, the CAC grew to take on more of the project leadership, enhancing the community's ability to build an environmental health infrastructure and feel more ownership over research efforts of their people. The CAC developed committees for education, research and publications, and management. The CAC also became a source of local knowledge for scientific analyses and educational/outreach efforts.

Matsunaga et al. described the community advisory committee as an essential feature for conducting culturally-appropriate research. This committee was involved before the project conception. The authors wrote, "This project grew out of a planning process which stimulated the formation of a community research committee composed of community representatives, health professionals, and scientific researchers, that worked for two years to develop and seek funding for the Wai'anāe Cancer Research Project. A five year proposal for breast and cervical cancer control received funding from the National Cancer Institute in 1990."

Once the grant was funded, another community advisory committee was organized by project staff at the community health organization. The community health organization was the direct recipient of the grant and its medical director was asked to serve as the principal investigator. A community leader and the director of the university's cancer research effort were co-principal investigators. Two representatives of the community advisory committee and two scientific representatives comprised the membership of the policy-making steering committee. In the event of conflicts, the principal investigator retained final decision-making authority. Community residents were chosen to participate on a community advisory committee (cac) based on their involvement with community health activities, their knowledge of Hawaiian culture and their understanding of the local community. Elders were asked to participate because they are considered the 'keepers of cultural knowledge and wisdom'. CAC members volunteered over a seven year period, as they were often very busy, smaller ad hoc construction crews would do special intensive tasks, i.e. mailings, telephone calls, etc.

Foster et al. studies on community review for genetic research invested much effort in organizing community representation for genetic research collaborations. The researchers conducted 150 ethnographic interviews in order to learn from the community who was consulted for making community health decisions. The authors wrote, "The interview included questions about who was consulted in making health-care decisions in order to identify private and public units considered by the community as the most appropriate entities to consult about the collective implications of genetic research. Appropriate is defined as the population's process for reaching communal consensus. The project relied on the survey and the input of the Apache elders. Members of the community were very aware of the issues of representativeness and referred the researchers to a public unit, the Apache Business Council, five person committee elected by tribal members which has the authority to make formal decisions about matters affecting the well-being of the community as a whole."

The Apache Business Council sponsored public meetings for the researchers to explain their research goals. The ABC appointed another committee to review the research proposal and to negotiate a subcontract with the researchers. First a tentative agreement was reached with the appointed committee and after two more months the ABC approved a final agreement as private discourses occurred in the extended families. The agreement includes funds to compensate the tribe for expenses of maintaining a CRB and helping to recruit volunteers. It does not obligate members to participate in research nor does it supplant informed consent by individual participants.

Summary of Community Advisory Committees

These case study examples outline a number of approaches for developing a mechanism for community partnership and/or collaboration that allows community members shared control over the research efforts on their people and protection from research abuses. The case studies demonstrate that there is no one standard approach for developing these committees. Several studies report on the organization of a committee by the community organization who is a partner in the research collaboration. The recruitment of members in each of these examples was informal and stressed those members who were community elders as well as those who had shown some commitment and activism around the research issue. One study assessed the community's opinion about who would best represent them in health-related decisions.

Once formed, these committees grow into a role of project leadership as they take on decision-making responsibilities and project work tasks. In reviewing the case studies, some of the authors discussed that community advisory committee members were paid for their participation, as they may have to give up work time for their participation. Some community members are frequently asked to be on committees so that significant portions of their time have to be spent on this participation. Other authors reported that the committees were voluntary. Some committees are small in size, 5 members, while some can be as large as 40 members. Most of the authors stress that it is important to budget for these committees in research grant proposals.

In the following sections, more will be included about the roles and responsibilities of these committees as the various ethical guidelines developed in these studies are reviewed.

(3.) Initial Administrative Arrangements between Researchers and Community Members

In conducting community-based or collaborative research, community members and researchers have adopted a variety of administrative arrangements guiding their working relationship. In the case studies reviewed, three different types of arrangements are indicated.

Partnership Agreements on Principles of Research

Herbert writes that even before letters of intent were submitted by the research team to funders, a set of working principles of research were established between the researchers and the community. These principles assure that this is a partnership project with provisions of accountability that the researchers will have to the community. Similarly, Macaulay et al. developed a Code of Research Ethics among three partners involved in research in the Native Mohawk community of Kahnawake. These partners included the academic partners, the community-based researchers, and the community advisory board of 40 volunteers. The first review was conducted by the Project staff and then given to the community advisory board for review. The authors noted that this process took eight months but was well worth the time as it gave everybody the opportunity to define their roles. The Code contains a policy

statement; principles of participatory research and the obligations of all the partners not just the researchers and provisions regarding control of data and dissemination of results. The mutual obligations stated include:

- *Obligation of Researchers*: Obligations such as written permission from the research subjects, anonymity, confidentiality, and scientific accuracy are common to all ethical guidelines, along with participatory research principles including a transfer of new skills to the community as a result of the research process and assistance with health or social issues that are raised by the research findings.
- *Obligation of the Community-based Researchers*: community-based researchers have the additional obligation of maintaining a long-term relationship of trust in their dual role as caregivers/educators and researchers.
- *Obligation of the Community*: These are to meet regularly with the researchers, to promote the objectives of the project; to offer advice for the intervention and interpretation of the evaluation; to control the data after the project has ended, and to write dissenting opinions, if needed, at the time of publication.

Quigley et al. discuss a set of participatory research principles guiding the interactions between the researchers and the community. These address the assurance of community participation in all stages of the research process; the need for qualitative research processes and data as well as quantitative analyses; that community observations be a valid source of data for environmental health research and that community education about the research and its findings be conducted. Quigley et al. discuss the sharing of research funding between the researchers and the community and the assistance of the researchers in developing community infrastructure; training staff and recruiting an advisory committee as part of the research process. Although the activities took place, there wasn't a formal code of research policies or research agreement to guide this.

Community-Generated Guidelines and Agreements

In a separate article, Macaulay et al. recommend that communities develop a separate checklist for their working arrangements with researchers. The checklist would assist them in determining if they truly understand the nature of the research; the question being researched, the expected benefits, the risks, terms of confidentiality, ownership of data.

The Akwesasne Task Force of the Environment has a more formalized process for ensuring the community's protection in the research process. They require all researchers interested in pursuing research in Akwesasne to submit a 5-page proposal to the ATFE Research Advisory Committee. These guidelines for writing this proposal ask the researcher to describe his/her plans for 12 items: research question, benefit to community, methods, confidentiality, disposition of data, risks, funding, cultural sensitivity training, equity, empowerment, intellectual property rights and data ownership/archive. The RAC has a review process where they either grant approval or withdraw approval of a project.

The Indigenous Peoples Council on Biocolonialism's Research Protection (IPCB) Act advocates the development of a community research advisory committee; a proposal submission process for the researchers to the advisory committee and an extensive model agreement for the conduct of research to be implemented with the academic or scientific research team.

Researcher-Community Planning Process for Research

Matsunaga et al. describe a planning process between the researchers and the community about potential future research. This process stimulated the formation of a community research committee composed of community representatives, health professionals and

scientific researchers. They worked together for two years before submitting a major proposal to the National Cancer Institute. In this process, they established roles and the governing structure of the project which was community-controlled.

Foster et al. highlight a communal discourse process in their initial engagement with the community, the Apache tribe of Oklahoma. They conducted 150 ethnographic interviews (20% of adults). The interview included questions about who was consulted in making health-care decisions in order to identify private and public units considered by the community as the most appropriate entities to consult about the collective implications of genetic research. Appropriate is defined as the population's process for reaching communal consensus. As discussed earlier, the Apache Business Council was considered the most appropriate committee to work with the researchers. The Apache Business Council then appointed another committee to work with the researchers for a subcontractual agreement. The completed agreement holds similar provisions to those included in the ATFE RAC: research scope, publications, intellectual property rights, data archive storage and study, and cultural concerns/cultural sensitivity.

Summary

In summary, the case studies indicate three possible processes for the engagement of community members and researchers in collaborative or community-based research. The first is the formal or informal agreement of research principles among the involved parties. The case studies show both a generalized approach for this to a more specific set of guidelines which delineate obligations and responsibilities of all the parties. In most cases, these principles are agreed to before any research activity gets underway. It is important to note as well, that these agreements are not necessarily always carried out with official tribal councils or representatives but instead include variation in the type of community partner. Community, environmental, health or educational organizations are represented as well as a tribal business council. The Native community partner is not always a government official entity.

The variations in the formality and informality of the agreements may be related to the amount of experience a community has had with working with researchers and the level of infrastructure in the community to deal with health or other researchers. The ATFE developed its guidelines after a decade or more of research experience. It is likely that it would not be appropriate to prescribe set arrangements for every community and to allow an organic process to emerge from each setting and its unique conditions.

(4.) Community Education on the Risks and Benefits of the Research Proposed

The stress on the need for community members to be aware of the risks and benefits of proposed research is a strong theme that occurs frequently in all the case studies. Although this is a topic in the area of informed consent, it is given separate attention here. Again, community members may engage in research only to find that it has ultimately brought harm from stigmatization or disruption of community relations or other unintended results. Internal Review Board's (IRBs) for academic research institutions often require statements of potential harm or risks to subjects but these are usually framed in terms of individual subjects not collective or community-based risks. Beauvais stresses the importance of providing of an adequate description of the research. The value of the research information should be explained at both the tribal and individual levels. This will lead to much less resistance and a higher level of cooperation and collaboration with the community.

The ATFE requires prospective researchers to explain in a proposal exactly what the intent and benefit of the research will be. They require a separate statement to be made about the risks; potential legal, financial, social, physical, or psychological risks and how these risks will be explained to the community and the study participants. Similarly, the IPCB's (2000) guidelines for Research Review Committees recommend that researchers make a statement of full disclosure of research benefits and harms to all relevant persons and organizations seeking to undertake research and that the research sponsors agree to address, satisfy and correct any concerns that are stated.

Quigley et al. discuss the need to educate the community on research options in environmental health; the benefits and the problems with various health study methodologies so that they can make informed decisions about which methodologies are appropriate for their community. Often communities remain at risk from contaminant exposures because scientists conducted crude studies with inconclusive or negative findings and no further follow-up is provided. Macaulay et al's Code of Research Ethics explicitly requires a discussion of the benefits of the research to the community. The Apache Business Council sponsored five community meetings for the Foster et al. research team to explain their research goals and potential risks and benefits to the community. The Apache community actually identified risks of stigmatization and discrimination but with certain protections in place, they decided in favor of the research for its potential benefits.

Foster et al. (1998:1723) describe certain culturally-specific risks which they reported were of higher concern to community members than employment or insurance discrimination. One such risk is the potential for genetic research to contradict the community's beliefs about its history or worldview. This could cause fundamental disruptions of social life. Foster et al. state that since psychosocial stress and disruption of family units are recognized by geneticists as harms, IRBs need to consider these, minimize them as much as possible and treat as legitimate research harms

Both informing the community and individuals about risks and benefits and addressing the concerns of risks of research with community members are critical ethical research practices. Several observations emerge from these case studies. One is that the researchers are predominately asked to evaluate the risks to the community. The Foster et al. article demonstrates that in community meetings, community members identified risks from the research efforts. Researchers and institutional IRBs may not be adequately prepared to know all potential risks to the community. A process for allowing the community to decide about the risks may be essential to this process. Secondly, it may take considerable effort to assist the community in understanding the full implications of a research effort particularly if the research approaches have very technical methodological approaches.

(5.) Community Involvement/Collaboration in All Stages of the Research Process

All the authors stress the importance of the community being involved from beginning to end in any research project. This includes the research design, (the research aims and methods) the implementation of the methods, the review of results, the interpretation of results, the dissemination of findings. In the case of the Akwesasne Task Force of the Environment, they are actually involved at the earlier stage of approving the research proposals and the researchers that come into their community. The ATFE RAC then requires progress reports to be given to them as the research is progressing. Davis and Reid highlight the feedback sessions during the research process to ensure correct collection and interpretation of the data and ongoing project evaluation. They recommend that American Indian professionals should be invited in for peer review with the project. In a number of cases, the community advisory

committee serves as the vehicle for ongoing reporting of the research effort. Herbert makes a similar point that analyses and interpretations be discussed with community health representatives in order to ensure accuracy and avoid misunderstanding. In that research project, community consultation took place in the form of discussions with key informants and traditional community celebrations which were held at the beginning of the project in each village. Focus groups were also held in each community.

Macaulay et al. reiterate the need for the community to be involved in a review process. Particularly they note that a lack of education should not disqualify community members from joining in constructive issues relating to the study and application of findings. Quigley et al. provided two three-day workshops/year for the community advisory committee to assist them in understanding concepts of environmental health research and the various technical research activities undertaken by the technical staff. With improved understanding, they were able to deepen the quality of their review and feedback and gain skills in environmental health research review.

(6.) Local Knowledge Incorporation and Validation

In addition to periodic reviews and community feedback sessions, several authors highlight the importance of incorporating the local knowledge of the Native community members as part of the research process. This was usually accomplished by involving community members as project staff for community-based outreach or community-based research. In their general terms of participatory research, Macaulay et al. have included a focus on the production of local knowledge to improve interventions and professional practices. Herbert encouraged community-based researchers to draw on the experience of community members so research interventions would be relevant and acceptable to the community. Research interventions, such as gathering traditional foods, then were more culturally appropriate.

Matsunaga et al utilized extensive networks of community staff and volunteers for their cancer research project. Traditional Hawaiian values and communication models were used to develop curriculum for promoting breast and cervical cancer screening. Local knowledge about community organizing amplified the project's ability to reach 500 women in the research service area. A number of environmental health studies carried out in Akwesasne included external and community-based researchers. The success of these research interventions was due in a great part to the gathering of interview data of the local inhabitants. These interviews were organized and carried out by the community-based Native researchers. The interviews are carried out in a more culturally-appropriate style and the data is more accurate and relevant to the research activity.

Similarly Quigley et al. involved community-based researchers for local knowledge collection about personal and environmental exposures from nuclear testing at the Nevada Test Site. The Native researchers were able to have access to interviewing the elder population which was critical to understanding the conditions in the 1950's. Moreover, the community-based researchers (and the community advisory committee) produced important data for exposure assessment analyses; such as dietary and lifestyle information that was much different from mainstream assumptions about what people ate and how people lived. The data collected by these researchers led to higher estimates of exposure from radiation contamination than was previously assumed. The local knowledge collection was also utilized in balancing the content of education modules for the community advisory committee and community members. This information was integrated into culturally-relevant presentations and educational materials. The community staff and the community advisory

committee also were able to guide the educational outreach for the project by identifying and attending local events and ceremonies most effective for the education outreach.

Scott and Receveur (1995) wrote that new areas of development in research ethics deserve particular attention to ensure that the research should take into account the knowledge and experience of the people. The authors particularly refer to research questions and data to be collected.

These authors bring out an important issue. The development of more partnership studies can demonstrate that researchers and communities can collaborate effectively when they both come together with their knowledge bases integrated as one. Researchers need to listen to the experiences of the local people and put this experience into their research methodology. They then can alter and modify their methods and questions to fit the local context. For example, many Native communities along rivers and oceans rely heavily upon fish for their daily subsistence. In their cosmologies, spiritually, the people and the fish have become related and share an obligation of reverence and care. Many of these fish habitats have now become very polluted and the fish contaminated. Instead of researchers solely investigating the levels of contaminants in the fish, they may reformulate their research approach to take into account the local concerns about a loss of reverence for the fish. Through interviews with the local people, an assessment could be made about the extent of damage sustained by the people from their inability to engage in traditional cultural and spiritual practices. The findings of the damage would be reported back to the people for the development of local solutions.

Although several case studies in this report do some of this integration, more examples are needed in the literature of models that integrate the experiences of local people with the research questions and methods.

(7.) Equity with the Community – Reimbursement/Incentives, Training, Other

Most of the authors stated the important issue of equity with the community in the conduct and execution of the research project. Maddocks writes that the community has the full right to recompense of expenses that they might incur in the research process; such as assistants, travel, utilities, etc. Community equity is implied in Macaulay et al. as the project is utilizing community-based staff and the researchers are obliged to transfer skills to the community. Herbert et al. state that equity in research refers to building an empowered community with equity of resources, capacity to solve problems, ability to identify problems and solutions, increased participation in community activities and a stronger sense of efficacy. This project utilized community-based research staff, as well.

Beauvais includes reimbursement and incentives as important conditions of research with a Native community. He states that financial and personal resources are extremely scarce in Indian communities and participation in research can often be an extra burden. Minor and major costs to the community must be recognized and reimbursed. Research budgets must be structured to take these types of expenses into account. In terms of incentives, he states that when research activities take a large amount of time for community members, it is necessary to reimburse them for that time and travel expenses. The amount must be equitable and commensurate with the time involved with the project; it should not be excessive. Too much reimbursement may be coercive and interfere with the subject's decision to participate in the project. It is important to ensure that the research effort returns some benefit to the community to overcome exploitation.

The ATFE has equity embedded in their definitions guiding the Akwesasne Good Mind Research Protocol. Equity is the sharing of resources; finances, knowledge, networks, personnel, and social and political power. In their guidelines for researchers, they require the researchers to budget funding for community education, outreach and cultural sensitivity training. Researchers must describe how the community participants in the research process will be given fair and appropriate return from the research; for example, obtaining copies of the research results, authorship of the study, acknowledgement, royalties, monetary compensation. Davis and Reid recommend that researchers should establish with community representatives a value exchange of their time, for example, skills, training, employment, and access to funding and mentoring.

Quigley et al. discuss “Building a Community-based Health Infrastructure” which includes sharing research funding with the community through a subcontract to a community-based organization; recruiting and training local Native staff and various Native consultants; the recruitment and training of the community advisory committee and an ongoing process of building community control and shared leadership. Shared authorship and community acknowledgements are evident in the article. Matsunaga et al. provide evidence of the economic benefits brought to the community - the community health center benefited from the sponsorship of the grant. Data analysis, scientific expertise, and some data collection services were obtained by the health center through subcontracts. This provided jobs and training for community members at all levels of the research (i.e. the telephone survey company recruited all Native interviewers).

(8.) Cultural Sensitivity Training

Several authors highlight the critical importance of cultural sensitivity training in the research process. Maddocks states that “sensitivity towards Aboriginal culture should be recognized and demonstrated in the methodology (e.g. awareness of the need to have female workers for studies involving Aboriginal culture, problems likely to be encountered in using photographic material.) The discussion by Beauvais on cultural contexts specifically is put forward to assist in improving cultural sensitivity on the part of researchers with Native communities. ATFE RAC requires researchers to participate in cultural sensitivity training “So that researchers are better prepared to work in our community, all principal investigators, graduate students and any others involved in data collection will be required to undergo cultural sensitivity training which will be provided at the researchers’ expense by the North American Indian Travelling College. Costs will be determined based on the scope of the project.”

Other authors seem to have an implicit understanding of the need for cultural sensitivity training but do not have a separate program component identified as such.

Macaulay et al and Quigley et al. emphasize a two-way training process in their community education activities whereby Native community members and external researchers inform each other about each of their cultural contexts and perspectives.

(9.) Informed Consent Issues: Confidentiality, Anonymity, Voluntariness

Several of the articles have an expanded discussion on informed consent issues regarding Native communities. For example, Beauvais brings forward these recommendations for informed consent for individuals:

- The subject must be fully informed of the nature and intent of the research, including any risks.
- After being informed about the research, the subject must freely agree to participate. The subject must also understand that they have the right to terminate their participation at any point during the research without any negative repercussions.

- The research must involve minimal risk to the subjects. The risks that exist should be outweighed by the benefits.
- If minors are involved, parents and guardians must give their consent and they should be fully informed of risks.

Beauvais questions whether consent has to be in writing or does the act of participation in a project after learning the risks imply consent? This issue emerged out of the difficulties in gaining consent signatures from a large number of parents for high school survey on drug use. Beauvais finds that current practices in informed consent will require parental signatures on anything that is not part of the school curriculum. Beauvais believes that when risks are minimal or non-existent that notification is necessary but not signatures.

The ATFE RAC proposal submission guidelines include a provision for ensuring confidentiality. “Describe how confidentiality will be protected. Indicate the circumstances in which the obligations of the researcher will constitute a breach of confidentiality. Describe how individual participants will be informed of the degree of confidentiality that will be maintained throughout the study. It should be remembered that unless otherwise specified, only aggregate data, not individual data, shall be published or released to the general public. All individual identifiers such as names, addresses and phone numbers must be kept confidential and no sale or transfer of data-bases outside the specific research project shall be allowed. You must state in your summary if the community of Akwesasne will be identified in any data released to the general public. “

Collective risks as discussed under the “Community Benefits and Risks” are a major concern for many Native communities. This area of informed consent needs more development for communities, IRBs and funding agencies. Foster et al. state that researchers need to realize that collective issues of risk cannot be addressed fully by informed consent. Among the Apaches, individuals may be prohibited from discussing community-specific issues outside the collective decision-making processes of the tribe.

In discussing community confidentiality, Beauvais states that it is essential for personal data to be guarded in Indian communities as those communities are small and this data could easily become public. Often findings from research in Indian communities can perpetuate negative stereotypes. As such, there is an absolute policy that school or community level data is not released to anyone but the collaborators at the local level. If information is requested from the outside, we require written permission from all the collaborators before it is released. The identities of schools or particular reservations are not released in aggregate publications.

Norton and Mason (1996) discuss community confidentiality and the need for protecting the community as well as the individual. These authors agree that specific communities should not be identified in professional publications. These guidelines were presented by Norton and Mason as suggested by Shore (1989),

- (a) a press release should be supported and initiated by the tribal government;
- (b) research findings should be supported as generalizations;
- (c) the identity of local communities should remain confidential and
- (d) the emphasis should be, as much as possible, on positive aspects of the findings.

Norton and Mason (1996) also state the confidentiality is also an issue within the generally small and close-knit communities that characterize this special population. They recommend

that tribally-sponsored projects that all employees sign agreements of confidentiality and receive training regarding confidentiality.

Foster et al. address two other key areas of informed consent: anonymity and the avoidance of coercion.

Anonymity: The option of making a research population anonymous may strike some researchers as a strike on their freedom of scientific inquiry. Restrictions on free speech generally occur when harm comes to others as a result. Existing ethical standards recognize the collective risks of entailed in the publication of family or kindred names in pedigree studies. The limit on the use of the Apache name is a natural extension of established protections regarding concerns of collective risks. By agreeing to allow Apaches to review research manuscripts before they are published and to request that the population be made anonymous allows us access for the conduct of research.

Coercion: The researchers emphasized that their study would be based on individual volunteers. A communal consensus in support of a research project constitutes collective willingness to promote the research, not a commitment of individual participation. One safeguard for individual autonomy is to provide privacy in collection procedures.

Voluntariness on the community level has come up in several articles. Macaulay et al. comment that communities need a way to suspend research activity if the project becomes unacceptable. The ATFE RAC reserves the right in their research protocol to withdraw approval from a project during the research process.

(10.) Data Control, Interpretation, Ownership, Publication and Dissemination

Issues of data control, interpretation of results, ownership, publication of results and dissemination procedures are often the most difficult areas of research ethics in these communities. Many of the authors have put forward their specific recommendations from their case study experiences.

Maddocks stresses six points regarding the “Ownership of Data and Publication” - (1) researchers have an ethical obligation to report findings to community (2) raw data belongs to the community (3) no publication should identify the community or individuals without permission (particularly photographs). (4) acknowledgement of aboriginal assistance; co-authorship is encouraged. (5) permission should be sought by researchers from community before comments are made about research to media to avoid derogatory or stigmatizing remarks. (6) a process for resolving disputes should be included.

Macaulay states that the trickiest issues in the community-researcher relationship are ownership of data and publication of results. In participatory research, researchers need to work within the political realities, fully disclose potential pitfalls at the beginning and listen to advice of the community; it takes longer but will be more satisfying.

Macaulay et al. firmly put forward in their Code of Research Ethics that the community controls the data both during the research process and after the research has ended. During the project the academic partners are appointed guardians of the research data. At the end of the project, the data must be returned to the community who will decide on its future uses. However, the community is obligated to offer the original academic and community researchers the opportunity to continue the analysis before the data is offered to new researchers. During the research, any new researchers, such as graduate students or

established investigators must apply to all three partners and be accepted by all three partners as well as consent to follow the Code of Research Ethics.

Another requirement of the Code guides the “Dissemination of Results”: There is continued sharing of power and control in the dissemination of results; including publication in scientific journals. In the case of a disagreement, the partner who disagrees with the interpretation of the data must be invited to communicate their own interpretation of the data as an addition to the main data, be it oral or written. All partners agree to withhold any information if the alternative interpretation cannot be added and distributed at the same time, providing the disagreeing partners do not unduly delay the distribution process.

Macaulay et al. conclude that community ownership of data, both during and after the process, prevents misuse of results. Managing dissent at the time of publication is an innovative feature, which provides a framework for discussion and negotiation and aims to avoid extreme solutions and unresolved disagreements.

Herbert et al. writes that if the community opposes the publication of any of the results (data or analyses and interpretations), the project team will not publish beyond its reporting requirements to the funding agency. The research team will ensure that any health or social issues that are raised by the research are addressed responsibly so they do not cause a burden for the CHR’s.

Beauvais recommends a prior agreement regarding publication wherein the community members have the right to review manuscripts prior to publication and can suggest modifications that protect the reputation of the community and its members. Collaboration with community members in the writing of the manuscripts can be extremely valuable; community members can provide interpretations of results that can enrich the research outcomes.

ATFE-RAC requires in their research protocol a description of the “Disposition of Data”. Specific items of interest here include

- how individuals will be informed of how data will be used;
- how individuals will receive their own personal results;
- how the community will be educated or empowered by this study;
- what manner will aggregate data and progress reports be shared with the RAC. They require that data is to be shared within the community before it is released outside the community.

Another requirement that the ATFE-RAC requires is a statement on “Intellectual Property Rights” including (1) plans for publication or commercialization of research results; (2) how will co-authorship be shared; (3) how the community will have access to data for their own use. Researchers must inform the RAC of all journals, publishing houses, conferences, etc. where they plan to share results. A process must be outlined to incorporate the critiques and reviews of the RAC of studies before publication, or release of results to the public.

“Data Ownership/Archive” is another concern of the ATFE RAC. The ATFE reserves the right to require deposit of all raw materials, data, working papers, etc. in a tribal repository with specific safeguards to ensure confidentiality.

Quigley et al. noted that the collection of local knowledge is a serious issue in their research partnership as there are risks of not only the exploitation of that knowledge but also the loss of privacy and cultural ownership of information. As such, the CAC is developing internal controls over data collection and use. All community members interviewed sign releases for the quotes or stories to be used anonymously in reports or publications. Additionally, cultural or spiritual information collected will be maintained in confidential files.

In the Matsunaga et al. study, community ownership of data was so important that a document was developed “Protocols for the Publication and Dissemination of (Project) Data”. These protocols call for (1) community participation in the interpretation of preliminary and final data; (2) the timely sharing of this data with research participants and Native Hawaiian community organizations (3) the participation of community representatives as co-authors on publications of data and (4) community-level peer review process established for submissions to scientific journals. Dissemination to other communities occurs through videotapes, summary findings, manuals and publications.

In discussing data management, Foster et al. state that all manuscripts that report project findings will be reviewed by the ABC CRB, which will have 60 days to raise objections to use of the tribal name. In that event, investigators could either revise the manuscript to satisfy Apache concerns or could publish the result without naming the Apache tribe.

In describing “Intellectual Property Rights”, Foster et al. report that according to long-established practice as well as limited legal precedent, individuals who donate biological materials do not have legal claim on the intellectual property obtained from them. In this project’s agreement, the owner of any intellectual property is the university, the sponsoring institution. The subcontract however recognizes the unique contribution of the community in the creation of that intellectual property and so the university will deduct 10% of royalties for legal and administrative costs. Of the remaining, the tribe will receive 30%, the university 30% and the investigators 30%. The unassigned 10% will be for a reserve fund for liability or litigation. The Apache CRB stated that its royalties would go for health education and promotion.

For the issue of “Archival Storage and Study “, Foster et al. claim that at the project’s conclusion, the researchers will negotiate with the tribal CRB the issue of long-term storage of biological specimens. If agreement cannot be reached, they will be disposed of in a culturally-appropriate manner. However, if the CRB permits storage of samples, explicit provisions will be negotiated to define how future research projects would receive community approval.

Apache cultural concerns include having restrictions about physical contact that are specific to gender, family, and age. Blood samples need to be drawn by non-Apaches. Procedures will be reviewed by the CRB for the respectful treatment of blood samples, which are still considered part of the body for the Apaches. Concerns about the publication of findings focused on the stigmatization of families with a history of diabetes within the community rather than discrimination from the outside. The primary concern about use of archival specimens was in the potential for a comparative study, comparing the Apache genome with other Native peoples. These results could contradict Apache origin narratives as these risks are based on how Apaches culturally construct their own sense of shared identity not on how others view them.

Foster et al. discuss commercialization of research resources. They report that “though the sharing of research royalties is not standard practice; as a matter of equity the researchers believe that the tribe should share in financial benefits that come about due to its unique genetic resources. Without doing so, socially identifiable populations may feel exploited. “In regards to future studies of archetypal samples, Foster et al. state that this community prefers to see how research is progressing before making a decision on the treatment of archetypal samples. The researchers agree to periodic reports to the community on its findings. It is important for community control of the samples to be retained to reduce their collective risks.

Summary

In summarizing the case study recommendations regarding these various issues about managing research data and intellectual property rights, these major trends can be concluded. Many of the studies recommend that community data should belong to the community and that communities maintain control over this data. The mechanisms of how the communities are to do this however are not well-developed. Most of the authors recommend the co-authorship and acknowledgement of community partners in the writing of publications. It is important to budget for the community partner to write publications in the research process. In implementing community review procedures of the research findings, there was agreement among the authors for developing community dissenting and critiquing procedures. However, there is some disagreement on how far this should go. Some authors recommend that the community write a dissenting position and one author stated that the research should not be published if the community is displeased with the research findings.

Several authors recommend that there be community approval of presentations of data outside of the immediate research and community context. Sets of procedures and protocols should guide this activity. The case studies demonstrate various arrangements for shared or single institution control over intellectual property rights.

(11.) Longevity and Follow-up

Several of the authors discussed the importance of some efforts at sustainability by the researchers. As was stated in the section of the “Historical Context of Research”, researchers are often seen as parachuting in and out of these communities. Short-term research efforts that open up problems and needs in the community and then leave the community on its own to deal with them after the research project has ended has been another major ethical problem. For example, Herbert et al. cites complaints of this by the community health representatives that a research project raises issues for a community such as painful memories of loss of culture after European colonialism that community members would be left to deal with after the project has ended without the necessary resources to do so. Herbert et al. recommends that any health or social issues that are raised by the research are addressed responsibly so they do not cause a burden for the community health representatives.

Beauvais addresses the issue of project longevity. He states that often research projects are short-lived, 3-5 years, then the researchers leave and the community is left to continue an effort with meager resources. Efforts for extended funding should be part of the research plan with communities. Quigley et al. write about a “Community-based Hazards Management Plan” as an objective of longevity worked into the project. The project was able to gain additional multi-year funding by focusing both on short-term and long-term goals.

In sum, long-term sustainability for a research effort should be a major consideration in a research effort. A short term research effort that has potential to open up many issues for

community members without follow-up or continued finding should warrant careful consideration.

(12.) Impact and Empowerment

Several of the participatory research projects included in the case studies highlighted positive impacts from their community-based research efforts. Some of these are included here to provide justification and evidence of the benefits of a participatory, collaborative engagement between researchers and community members.

Herbert's Haida Gwaii Diabetes Project emphasize that researchers and community members shared resources; that the community showed the capacity to solve problems; increased their participation in community activities; had a stronger sense of efficacy to influence social change. Partnering occurred in focus groups held in each community to discuss the meaning of diabetes, living with the illness, ideas about causation and prevention and traditional approaches to healing. New interventions included a walking group, a group to gather traditional foods, and the allocation of budgets for managing and preventing diabetes. Another important outcome was the benefit to researchers who became increasingly aware of what it means to work within an educational approach that focuses on enhanced problem formulation and decision-making skills.

Montour et al. reported on the effectiveness of their effort in returning research results to the community. A specific focus of the project was on ensuring the proper dissemination of research results to the community. The project had discovered that that 48% of the Indian people with diabetes also had heart disease; 71% had hypertension; 86% were obese and 22% of the people without diabetes had ischemic heart disease. The researchers found that these results were depressing and decided to present the results in the wider context of the diabetes problem. They presented results in a one-hour session that was repeated several times for various community groups. Results were also presented during a talk show in a community radio station. Formal presentations reached 240 people; the radio audience number is unknown.

The number of people who arrived in the clinic for screening increased; the dietician was swamped by self-referrals (for dietary changes, weight loss and exercise advice. Junk food was banned from the schools. Staff and students began a daily exercise program. Parents were invited for this education about diabetes. Public pressure was exerted to build a walking, biking, jogging path along the St. Lawrence Seaway. Montour et al. demonstrate that appropriate health education of research results can have strong positive benefits for the community.

Quigley et al. provide an extensive list of positive outcomes both for community capacity-building and improved scientific analyses from qualitative research efforts. They stress the building of training and occupational opportunities, increased community capacity-building in the management of a community-based environmental health infrastructure. There were many achievements in community education about radiation risks and the increased literacy of community staff, advisors, and other community members in the health impacts of nuclear contamination. Quigley et al. also report on building community literacy in understanding the benefits and problems of various health research methodologies.

In terms of research outcomes, it is notable to point out that local knowledge data about dietary and subsistence activities of Native community members in the 1950's that came from

the interviews of Native researchers led to improve scientific analyses about exposure assessment. Community-based researchers highlighted the importance of Native people conducting interviews of their own people. A final important outcome was the community-based planning process for developing long and short-term goals for the future management of health impacts of radiation exposure.

In the Matsunaga et al case study, more than 500 women participated in the Kokua groups. All evaluation measures indicated that the project was a success; it served the population it needed to reach and had community-wide impact on the knowledge, attitudes, and behaviors related to breast and cervical cancer control. The following is a list of community benefits that were identified. (1) Direct economic benefits – the community health center benefited from the sponsorship of the grant. Data analysis, scientific expertise, and some data collection services were obtained by the health center through subcontracts. This provided jobs and training for community members at all levels of the research (i.e. the telephone survey company recruited all Native interviewers). (2) Improvements in Health Services and Systems – the project provided cancer reeducation and screening, developed a new evening screening clinic program and a Cancer Support Group. These are now regular services of the health center. Local funding was obtained for a Women’s Health Network which will build on enhanced community capacity-building for peer education. The funding will continue these services for the next three years. (3) Improved research capabilities – a document, “Principles and Guidelines for Participatory Research was developed, published and piloted during this project. It is now used for current research requests. The project served as a training ground for high school and university students, as a result, there is now a cadre of community women with research skills and experience, along with health research professionals who are trained in participatory research.

These examples provide some key results of participatory planning and research among community members, researchers and community staff and advisors. Participatory community collaboration is essential to improving the relationships between researchers and the community and overcoming past research injustices.

V. Conclusion

In this compilation of research ethics issues with Native communities, this paper brings forward a number of innovative methods for the engagement of research activities between community members and researchers. These methods are extremely important for allowing community members a meaningful and empowered role in the conduct of research in their own communities. Some of these proposed methods and terms of agreements are new and will need review and evaluation over time in order to assess their effectiveness. In particular, issues regarding disclosure of research results, rights of informed consent on the community level in addition to the individual level, types of partnership arrangements in the carrying out of research methods, and the development of alternative research approaches based on community ways of knowing will be important developments to improving equitable research practices in the field of environmental health. All the innovations proposed in this compilation should be informative to all involved in environmental health research with community populations in the future.