Author's Commentary on "Informed Consent and the Collection of Biological Samples from Indigenous Populations"

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Background

Questions 1-3

References

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Depending upon one's point of view, this case study might be viewed as either an exciting foray into new ethical territory or a marginally interesting development of issues only obliquely related to the more important core issues involving the notion of informed consent. I think both interpretations are hasty: While the case does highlight some newer elements, I believe it also illuminates issues central to a complete discussion of informed consent, and, what's more, does so in a way that provides a fresh perspective on some of those core issues themselves.

Contemporary events are, effectively, forcing more indigenous populations into working relationships with scientists. The supply of basic medical care, the HIV pandemic, drug testing and global projects such as the Human Genome Diversity Initiative (which seeks to catalog extant human genetic diversity) are all contributing to the greater rapport (or lack thereof) between western science and indigenous populations.

This case study was inspired by a controversy involving the patenting of an indigenous human cell line. An anthropologist working with the Hagahai of Papua

New Guinea jointly filed a patent claim with the NIH in order to (ironically enough) ensure fair compensation for the Hagahai in case the unique characteristics of their blood turned out to be profitable. The response was a general outcry about "patenting life" and scientific "biocolonialism." While these are timely issues in need of discussion, what struck me was the relationship between the Hagahai and their western contact. In particular, it struck me that the "informed consent" of the Hagahai was based almost entirely on *trust* -- they trusted "their anthropologist" to represent their interests to the NIH and the local government; they trusted that they would not be exploited; and they trusted her word on what it meant for the NIH to "[find] a virus in our blood and make a map of it." (*Cultural Survival Quarterly*, p. 33) This level of trust and the concomitant level of personal integrity and responsibility that go along with it are a lot to ask of anyone. Given the increased competition for funding in science, the pressure placed upon neophyte scientists, and the increasingly complex context of scientific research, how can the scientific community, Institutional Review Boards (IRBs), and funding agencies work toward safeguarding the integrity of the relationship between investigator and indigenous human subject? And what can a careful consideration of this question teach us about "informed consent" in more traditional contexts?

Questions 1-3

Question 1. It is generally agreed that any scientific research involving human subjects should strive to obtain "informed consent" of each individual participant. As a beginning point, we might define this concept as follows:

> Consent is informed when it is given by a person who understands the purpose and nature of the study, what participation in the study requires the person to do and to risk, and what benefits are intended to result from this study. (CIOMS, 1991, p. 11)

This definition focuses on the adequate disclosure of information by the investigator to the prospective participants. But two additional components need elaboration: comprehension and voluntariness. (Belmont Report, p. 6)

Comprehension is implied in the above definition by the word "understands," but its significance needs to be stated more explicitly. In particular, the criterion of

adequate comprehension requires the investigator to accomplish two things: 1) to provide requisite information in an appropriate manner (for example, free of jargon or specialized concepts) (Belmont Report, p. 6) and 2) to be aware that adequate comprehension cannot simply be assumed to be the responsibility of the participants -- i.e., the burden of ensuring adequate comprehension lies with the investigator.

Voluntariness distinguishes between mere agreement to participate and voluntary assent. Thus this component of informed consent forbids the use of coercion, undue influence, or any other means by which prospective participants might be pressured into agreement (Belmont Report, p. 6). As defined in the Belmont Report, "coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance" [Belmont Report, p. 6] and "undue influence. . . occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance." [Belmont Report, p. 6]

Informed consent, then, comprises three elements: providing prospective participants with adequate information, ensuring their adequate comprehension of that information, and refraining from actions that might compromise their ability to freely choose to participate. This notion of informed consent is meant to apply to a wide range of scientific activities and contexts. With respect to the present case study, however, the third component, voluntariness, proves the most relevant for evaluating Tiptree's actions.

Question 2. Informed consent is most often associated with individual participants in a given study. But indigenous populations present a unique situation, in that investigators will need to deal with both governmental authorities of foreign countries as well as more local authorities with special cultural significance. Two issues arise in this context. First, must an investigator secure permission of both national and local authorities? It is very likely that some sort of official permission from the national government (or its science agencies) will be needed. But that "official" governmental permission may have little or no value with the local group exercising authority for an indigenous population -- especially given the frequently "strained" relationships between national governments and their indigenous populations.For example, in their statement concerning the patenting controversy noted above, Yokotam Ibeji and Korowai Gane, members of the Hagahai people, write: "Part of (this money) does not belong to the PNG [Papua New Guinea] government, no way. Why (should they get the money) when they get money and

do not think about us, the Hagahai? No way. . . . They (the government) just think about themselves." (Cultural Survival Quarterly, p. 33) The different roles and interests of both groups may need to be considered. And in cases where an indigenous population is or has been exploited or oppressed by its national government, the issue of voluntary choice may stand in need of especially careful evaluation.

Second, investigators may have to comply with additional ethical guidelines or specific formulations of concepts and rules that will replace their American counterparts.Cf. DHHS and NIH Code of Federal Regulations, part 46 (Protection of Human Subjects), Section 46.101, paragraphs (b)(6)(g) and (b)(6)(h)]. This requirement reflects the fact that there are no universally accepted ethical guidelines for experimentation involving humans and no internationally recognized body for the ethical review of research involving human subjects.Cf. Law, Medicine, and Health Care, p. 160, which suggests establishing such an international committee.

The first issue is relevant to Tiptree's circumvention of the Yuchi council of elders. In particular, it points to a consideration of the status of the council of elders and their authority relative to their constituency and the local government officials. Insofar as the council is a locally recognized source of authority, its decisions ought to be respected. By ignoring the council's denial of permission to collect samples, Tiptree essentially violates the right to self-determination and autonomy of the Yuchi people. Even if the people themselves were completely open to giving blood, but the council opposed it, the council's decision would have to be respected. This conclusion follows because, presumably, the council has been chosen and empowered to represent the interests and well-being of the community. As such, it is the council that must bear the burden of deciding, in certain cases, what course of action would best serve Yuchi interests and well-being. If all the people disagree with the council's decision, then that is a matter for the group as a whole to work out -- it certainly doesn't license Tiptree to collect his samples.

The case study implicates the local government officials as the impetus for Tiptree's actions. As implied above, however, national governments may actually have interests and agendas that stand to benefit from undermining the authority of local bodies of authority, such as the Yuchi council. In this interpretation, Tiptree could be seen as a naive pawn in a political struggle. However, for the reasons set out in the last paragraph, his actions would still be deemed unethical.

Question 3. Now we are asked to assume that the council does sanction the collection of blood samples, but requires Tiptree to obtain consent of family heads and family members. In this way, we can scrutinize Tiptree's three strategies in light of the discussion of informed consent in Question 1.

My intention in providing three strategies was to form a continuum from least objectionable to most objectionable. Let me briefly discuss each strategy.

- Strategy 1: All other things being equal, I believe this strategy is unobjectionable. Tiptree attempts to provide adequate information to prospective participants while at the same time discussing the potential benefits of his work. Assuming the details are provided in an appropriate manner and that there is adequate comprehension, this strategy would serve as a prelude to voluntary assent.
- Strategy 2: This strategy is, at best, borderline. By offering poor families "incentives" or "compensation" in the form of valuable items or cash, this strategy verges on undue influence. That is, the form of the compensation Tiptree is offering might be "excessive, unwarranted, inappropriate or improper" (see above). Because the families are in a compromised position, their compliance might not be voluntary. The distinction here might be expressed as that between "buying consent" versus "reasonable compensation" for participation.
- Strategy 3: This strategy is clearly wrong. By arguing that the families "owe" something to Professor Kroeber and then "intimating" that future help would be withheld, Tiptree is basically threatening the families. This sort of coercion forces compliance at the price of voluntary assent. By abusing his position of authority and privilege, Tiptree sets a particularly poor example for others and jeopardizes the long-term prospects of other researchers hoping to work with indigenous populations.

Therefore, given the details of the case study, even if Tiptree did have the full consent of the council to proceed with blood sampling, the manner in which he obtained consent was clearly improper and blameworthy.

References

- The Council for International Organizations of Medical Sciences (CIOMS). *International Guidelines for Ethical Review of Epidemiological Studies.* Geneva: CIOMS, 1991.
- *Cultural Survival Quarterly* 20 (No. 2, Summer 1996) [Special issue on "Genes, People, and Property"].
- Department of Health and Human Services (DHHS) and National Institutes of Health (NIH). *Code of Federal Regulations, Part 46--Protection of Human Subjects.* 1991.
- *Law, Medicine, and Health Care* 19 (Nos. 3-4, 1991) [Special issue on "Research on Human Populations: National and International Ethical Guidelines"].
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* OPRR Reports, April 18, 1978.
- North American Regional Committee--Human Genome Diversity Project. *Model Ethical Protocol for Collecting DNA Samples.* 1997. Available at: http://www.stanford.edu/group/morrinst/hgdp/protocol.html.