Informed consent and the 1968 Neel expedition

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The Peacock Report raised the question of informed consent in connection with Tierney's allegations regarding Marcel Roche's experiments with radioactive iodine among the Yanomami beginning in 1958. The Task Force awaits material from Venezuela regarding these experiments. However, the question also arises in connection with Neel's expedition, since Neel collected biological materials among the Yanomami that remain under study. Thus it is important to evaluate whether or not these materials were collected with appropriate attention to informed consent. In discussions of the informed consent procedures that were used during Neel's 1968 expedition, it is important to recognize both the codes that were in force governing consent during that time and also to understand the way in which consent was actually obtained by researchers working with similar populations during that time period.

Important codes regarding informed consent in 1968

There are several excellent reviews of the history of informed consent by ethicists, philosophers, attorneys and historians of science (Beecher, 1970; Tranoy, 1983; Engelhardt, 1986; Faden and Beauchamp, 1986; Beauchamp and Childress, 1989; Gert, Culver and Clouser, 1997; Doyle and Tobias, 2001). Discussions on the history of informed consent often distinguish between the consent practices of practitioners of clinical medicine and the consent practices of researchers using human subjects. The earliest authors of treatises on clinical medical ethics were guided by the principle of beneficence and dealt very little with the principle of autonomy. Standards for research using human subjects began as a reaction to the medical experimentation of Nazi Germany. The ethical principle of respect for persons or autonomy was of primary importance in the resulting Nuremberg Code. This principle of autonomy was then - and continues to be -- articulated as voluntary or informed consent.

The Nuremberg Code became the model for many of the governmental and professional codes formulated in the 1950s and the 1960s, even though it presents an ideal without detailing the particulars of application. Among the most important codes and laws during this time period include the 1953 National Institutes of Health (NIH) Clinical Center code, the 1962 Drug Amendment Act and the 1964 Helsinki Code. All of these codes deal with the issue of informed consent. The Helsinki Code was formulated by the World Medical Association and was used by many other agencies to develop their own guidelines. Unlike the Nuremberg Code, the Helsinki code distinguishes between therapeutic and non-therapeutic research. In 1966 the U. S. Public Health Service instituted a requirement of peer review of research, however, this was entrusted to the local institution and there was little oversight.

These codes were often difficult to apply. It was not until the 1970s that additional clarifications and standards were set. In 1971 the Department of Health, Education and Welfare issued guidelines for human subjects research. In 1974 Congress created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The commission was charged with developing a new set of guidelines for human subjects research. These guidelines became known as the Belmont Report. The report and the principles it represents, autonomy, beneficence and justice, have been codified into federal regulations and are routinely used by Institutional Review Boards (IRBs) in their analysis of research protocols. The National Research Council continues an on-going examination of ethics issues and prepares updated guidelines. More recently, the National Bioethics Advisory Commission established by Executive Order in 1995 was charged with making recommendations to the National Science and Technology council regarding both clinical and human biology and behavior research.

Neel's 1968 expedition to the Yanomami took place several years before the articulation of the bioethics principles in the Belmont Report. Although there were guidelines, the ways in which researchers obtained consent and explained risks and benefits were not firmly established.

One of the first documents to discuss the relationship of an investigator to a "non-westernized" study population was a 1964 World Health Organization (WHO) report. In 1962, the WHO convened a study group of scientists to discuss the organization of studies of "long-standing, but now rapidly changing, human indigenous populations". The resulting report, "Research in Population Genetics of Primitive Groups" (*WHO Technical Report Series*, 1964), was authored by James Neel. In the report Neel discusses the relations of the research team with the population studied. The study group met again in 1968 and produced a second report, "Research on Human Population Genetics" (*WHO Technical Report Series*,

1968), again authored by Neel, reiterating, with slight modification, the principles of the first report. The report states:

> Any research team has certain ethical obligation to the population under study. The investigator should always be bound by the legal and ethical considerations governing the conduct of medical and biological research workers. It is essential that harmonious relations be maintained both during and after each research visit. From previous field experience, the following factors have been found to be especially important.
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> (a) The privacy and dignity of the individual must be respected at all times and the anonymity of subjects must be maintained in publications. The comfort and individuality of subjects must be safeguarded, e.g., some people are unwilling to queue, or to have others present during examination or questioning. Care should be taken that individuals do not undergo an excessive number of examinations at any one time.
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> (b) Satisfactory reward should be provided for the subject's participation in the research and for any services provided. The nature of the recompense should receive careful consideration. The advice of local authorities may be invaluable, both on this question and in general, so as to avoid giving offence through ignorance of local customs.
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> (c) The local population should benefit from such studies by the provision of medical, dental and related services.
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> (d) The maintenance of congenial social relationships will be enhanced by methods suitable to particular areas, e.g. eating with families on occasion, exchange of information.
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> (e) All groups have learned individuals, e.g., experts on oral traditions and those with systematized knowledge and interpretations of natural phenomena. Consultation and exchange of information with such persons will often be of immediate value to ensure good relations and lead to the appreciation of the achievements of such peoples. Such information is pertinent to their cultural and therefore biological history.
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> (f) There should be the utmost regard for the cultural integrity of every group. All possible measures should be taken to prevent the activities and presence of the research team from adversely influencing the cultural continuity of the population being studied.

Issues of research involving indigenous populations were not examined in depth again until the United Nations Working Group on Indigenous Populations began meeting in the 1980s. Discussions in the United States in the 1990s on research among indigenous peoples were triggered by the 1990 Native American Graves Protection and Repatriation Act (NAGPRA) and the planning of the Human Genome Diversity Project. The National Research Council and the National Bioethics Advisory Commission both issued reports on research initiatives in the late 1990s.

Practices Relating to Informed Consent

In order to determine the practices of researchers in the late 1960s regarding informed consent, El Dorado Task Force member Trudy Turner surveyed a number of individuals who were active in the field at that time. The determination of individuals to consult was made by consulting various journals (*American Journal of Physical Anthropology*, *American Journal of Human Genetics*, etc.) to see who had published on genetics of indigenous populations in the late 1960s and early 1970s. Among the individuals responding were:

Alan Fix	William Pollitzer
Jonathan Friedlaender	Francisco Salzano
Eugene Giles	Jack Schull
Henry Harpending	Emoke Szathmary
Geoffrey Harrison	Kenneth Weiss
Newton Morton	

Individuals contacted did research in the following areas of the world and with the following listed populations and nations.

Ayamara	Solomon Islands
!Kung Bushmen	Canada

Japan	United States
Brazil	Haiti
Micronesia	Malaysia
Venezuela	Ethiopia
Paraguay	New Guinea

Each individual was asked the following three questions:

1. How did you attempt to get informed consent from individuals?
2. Did you have discussions about informed consent while you were in the planning stages of your research?
3. Did you exchange/reciprocate anything for samples?

1. How did you attempt to get informed consent?

Although there were some differences in responses about how information was conveyed to individuals, all of those surveyed stressed that voluntary consent was assumed since some individuals in the population elected not to participate. Some of the respondents indicated initially that they had approval from national or regional governments in the appropriate regions to conduct the research, while others dealt with the population or individuals. The leaders of the group under study were often consulted first and their approval was sought. If the researchers worked with medical personnel, the medical personnel were often responsible for obtaining consent. If they were not accompanied by medical personnel, researchers told the individuals/groups that they could not provide medical assistance. In every case some explanation of what the individuals were looking at in the blood samples was provided.

2. Was there any discussion of consent in planning stages of project?

Everyone said there was no discussion in the planning stages of the project.

3. What was given in exchange/reciprocity for samples?

If medical personnel were present, medical and dental exams were given. If a doctor was present, medical help or immunizations were provided. The following items were given: tobacco, candy, small sums of money, photographs, toothbrushes, bubble gum, powdered milk, rice, machetes or a community purchase such as a film projector.

It should be noted that Neel did consult with local authorities concerning remuneration before his field work among the Yanomami. In a September 20, 1966 letter to Reverend Macon C. Hare he states:

> "With respect to the matter of trade goods, I would say that it has been our custom after we have completed the work-up of each family to make its members a suitable present. Here I would repeat, as mentioned above, that we would rely on the advice of those in the field concerning what is appropriate to the present situation. We know by experience that we must do something to enlist the cooperation of the Indian, but, on the other hand, do not wish to upset whatever "economy" you have been attempting to establish"

The impact of Neel's work with the WHO

The participants in the WHO meetings on research with indigenous populations went on to conduct research around the world. Many were involved in the Human Adaptability section of the International Biological Program (IBP) (Collins and Weiner, 1977). The participants and their students worked in the Kalahari, the Andes, New Guinea, the Solomon Islands and other locations. Many of the respondents to the survey were under the IBP umbrella. The WHO document Neel authored reflects the standard of conduct for work with indigenous populations as well as the protocols for obtaining samples from populations.

Informed consent procedures of the 1968 Neel expedition

The Task Force has two primary sources of information on these procedures, provided by two members of the 1968 expedition who spoke Yanomami and who were therefore responsible for providing the information needed for informed consent. These are Ernesto Migliazza, a linguist specializing in the Yanomami language who accompanied the expedition, interviewed by Jane Hill, and Napoleon Chagnon, interviewed by Ray Hames. Migliazza and Chagnon have, as far as we know, not been in touch with each

other for many years. (Others who presented potential Yanomami subjects with this information included local missionaries who spoke Yanomami.) In a telephone interview with Hill, Migliazza stated that in each village, the Yanomami were told that the project would look for diseases that were "inside", "in the blood." In a conversation with Hames (2001b:2), Hames reports that in a telephone conversation conducted March 18, 2001, "[Chagnon] said that for a year prior to Neel's arrival and during the collection phase he told the Yanomamo in all the villages to be sampled that Neel's team wanted to examine their blood in order to determine whether there were things that indicated whether or not they [had] certain kinds of diseases, especially *shawara* (epidemic diseases) and that this knowledge would help treat them more effectively."

Migliazza observes that the Yanomami were accustomed to having their blood drawn, since Ye'kwana paraprofessionals visited Yanomami villages regularly and drew blood and administered medications to treat and control malaria. They were, however, amused and surprised that the Neel expedition also collected nasal mucus, sputum, urine, and feces samples.

Migliazza believes that the Yanomami found the trade goods offered by the expedition in exchange for samples to be overwhelmingly attractive. Neel had consulted with local missionaries about the type and quantity of compensation, and was following their recommendations in offering as compensation machetes, axes, cooking pots, and other goods.

We believe that the informed consent techniques used by the 1968 expedition would not measure up to contemporary standards. It seems clear that both Migliazza and Chagnon saw the statements that were offered to Yanomami as "explanations." They did not mention that the procedure included components that would be required today, such as clear information that nobody was required to participate in the study, that any subject could withdraw from the study at any time, or an explanation of possible dangers to subjects stemming from participation. Contemporary standards also require a very careful consideration of compensation, such that the kind of compensation offered not be viewed by subjects as so attractive as to constitute a sort of coercion. It is extremely difficult to adjust this standard to a situation such as that faced by the Neel expedition, working with subjects who lived in the direst poverty and in desperate need of material goods. Another very difficult question, which probably was not solved by the Neel team and remains as a dilemma for contemporary researchers, is the problem of whether lower-ranking members in a community, such as women and children in the Yanomami villages, in fact enjoyed the type of autonomy that would permit them a free choice as to whether or not to consent to participate in the study. It seems clear that Yanomami men viewed the machetes, axes, and other goods offered as compensation by the Neel expedition as highly valuable trade goods, useful in developing male networks of alliance. These goods, while attractive as well to women (who use machetes and axes in their own work) did not have the same meaning for them as for men. It is likely that women and children experienced coercion to participate in the study from their adult male relatives, and so were not fully autonomous consenting research subjects.

Another question has been raised by the Yanomami themselves. They believe that the consent procedures, which many people remember, carried an implication that they would receive medical care based on the findings of the expedition. They believe that such medical attention has never been forthcoming. Members of the Task Force agree that the "explanations" described by Migliazza and Chagnon carried such an implication. We point out that it was based on the results of research before 1968 that Neel identified the danger of a measles epidemic, and also that Neel continued to send vaccines and other medicines to missionaries working among the Yanomami through at least 1970. Furthermore, medical treatment was provided to the Yanomami on-site by the three physicians who participated in the 1968 expedition.

Informed consent procedures today also would usually offer subjects an opportunity to be informed of the results of the study. The Yanomami believe that they should have been informed about results, and believe that they were not so informed. We are not aware of any efforts by Neel to "follow up" with information on study results designed to be intelligible to interested Yanomami.

In summary, judged against the standards of 2002, the "informed consent" procedures used by the Neel expedition were minimal. However, judged against the standards of 1968, the use of procedures such as an explanation of the purpose of the research provided to subjects, considerable care in determining appropriate compensation, and the provision of some follow-up medical attention, were appropriate and even advanced. The Task Force observes that at this period many citizens of the U.S. and Europe were the unwitting and uninformed subjects of medical research; the Yanomami in fact received more explanation and compensation than was typical at that period.

Resources on informed consent procedures

Publications on Informed consent are available from the National Research Council of the National Academy of Science (http://www.nationalacademies.org/nrc) and the National Bioethics Advisory Committee (http://www.bioethics.org). The charter of the NBAC has expired but the papers are still available on line. In addition, the AAA Committee on Ethics Draft Briefing Paper on Informed Consent cites other sources.

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