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New Questions About Management and Exchange of Human Tissues at NIH
Indigenous Person's Cells Patented

Issue: Human genetic diversity (especially that of isolated indigenous communities) is a matter of increasing scientific, commercial, and military interest. The flow of human genetic resources among military and civilian researchers across international borders is unmonitored and unrestricted despite its value and significance. Analysis of events surrounding the U.S. government's patent on the cell line of a Hagahai man from Papua New Guinea, and the intellectual property claims on citizens of the Solomon Islands show critical shortfalls in medical ethics, human rights provisions, and intergovernmental protocols with substantial economic and political implications.

Policy Implications: The World Health Organisation (WHO) should establish internationally-accepted medical ethics protocols covering the commercialization or patenting of genetic material obtained from human beings. No agreed ethical rules exist. The Convention on Biological Diversity (CBD) should come to grips with its legal obligation to conserve and protect human biodiversity and to establish binding procedures for the international exchange of human genetic resources. The flow of human biodiversity in the mid-90s is at a level reminiscent of the flow of plant genetic material twenty years ago. The international community needs to act quickly to avoid similar (though more profound) mistakes. Finally, human tissue samples collected by U.S. government medical researchers flow freely to both private sector and military (biological warfare) researchers. The interest of U.S. Navy and Army researchers in HTLV-infected human cell lines from around the world is a cause for international concern and could be addressed during the Fourth Review Conference of the Biological Weapons Convention when it meets in Geneva in November.

Economic Stakes: Patented gene sequences and cell lines generate enormous profits for the life industry. A single sequence can be worth U.S. $1.5 billion per year, and more than a thousand patents on DNA sequences have been issued to over 300 groups.[1] While fewer cell lines have been patented, they are potentially equally valuable. The University of California-patented "Mo line" may also be worth billions. Rights to asthma treatments derived from research on isolated populations' DNA have sold for U.S. $70 million,[2] while academic researchers have received "gifts" from industry of over U.S. $12 million to further their collection of isolated peoples' tissues.[3] In cases where the actual biological materials of isolated peoples are not patented, their samples are pivotal in valuable new research, such as a new U.S. government patent on Alzheimer's and Parkinson's disease genes.[4]

INTRODUCTION

On March 14, 1995, the United States Patent and Trademark Office (PTO) ushered in a new and outrageous era in intellectual property by issuing a patent to the U.S. National Institutes of Health (NIH) for an unmodified human cell line drawn from an indigenous person from Papua New Guinea (U.S. 5, 397,696). It is the first time that an indigenous person's cells have ever been patented and has resulted in global outrage.

After discovering the patent, RAFI quickly moved to make the information public through a press release and began an intensive investigation to update our work on cell line patents from 1994 (see *RAFI Communiqué*, Jan/Feb 1994). RAFI filed for release of information about the patent under the U.S. Freedom of Information Act (FOIA) and after inquiries from NGOs and peoples' organizations in other countries (most notably Colombia) also investigated the management and sharing of human cell lines by NIH. The results have raised startling new questions about the ethics of such research and demonstrated concretely how indigenous peoples' cells are being reproduced and shared with a variety of institutions, including the U.S. military.

RAFI's press release and work to bring the issue to the Convention on Biological Diversity (CBD) provoked a storm of international protest aimed at the U.S. government, even among the U.S.' most staunch supporters. One senior official of the British government called the patent "disgusting".[5] These sentiments were echoed at the Jakarta meeting of the CBD in November, where several governments took the floor and denounced the patent. Ruth Liloqula, the CBD delegate of the Solomon Islands, also speaking on behalf of the Papua New Guinea (PNG)

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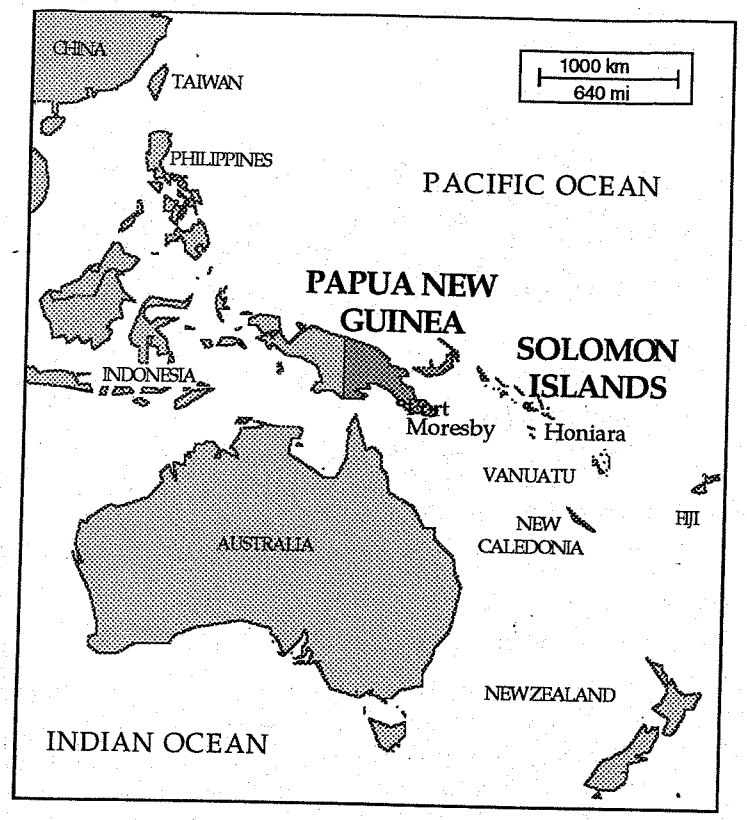

government, said "We are outraged by the recent patent and patent claims of human cell lines of our people."

Under pressure from NGOs and indigenous people, the U.S. government initially shied away from patenting indigenous peoples cells, withdrawing a 1993 patent application for cells from a Panamanian Guaymi woman. But despite official government indications to the contrary, behind the scenes NIH doggedly pursued the PNG patent application until their ultimate "success" last year.

"We are outraged by the recent patent and patent claims of human cell lines of our people."
--Ruth Liloqula, Solomon Islands Delegate to the CBD

Under FOIA, RAFI has obtained U.S. government documents outlining precisely how Hagahai cells, with potential for diagnosis and treatment of leukemia and related retroviral diseases, came to be the exclusive property of the U.S. government. We present the results of our research and a detailed chronology of events here.

Pieces of indigenous and remote rural peoples' very bodies are now, without any doubt, the potential "intellectual property" of the corporations and governments researching them in the North. The PNG patent and RAFI's research on the exchange of human cell lines dramatically underscores why groups like the Human Genome Diversity Project (HGDP) can no longer hide behind claims to be collecting only for historical, cultural, or medical research. It is now clear that they are also potentially shuttling the cells, DNA, and other biological materials of people into the intellectual property portfolios and cashboxes of the life industries (see maps, pp. 10-12).

ANATOMY OF A BIOPIRACY

HOW DID CELLS FROM HAGAHAI PEOPLE WIND UP PATENTED BY THE U. S. GOVERNMENT?

In 1983, due to medical problems, the Hagahai initiated contact with the outside world by visiting Baptist missionaries who lived some distance from their homes. Shortly thereafter, in 1984, the Hagahai had their first sustained contact with outsiders when an evangelist with some medical training set up a camp at the nearby settlement of Yilu.[6]

That same year, a census team from Papua New Guinea's government arrived and took account of the Hagahai for the first time. The census team was accompanied by an American medical anthropologist, Carol Jenkins, who was affiliated with the PNG Institute of Medical Research (IMR), a statutory body of the PNG government. The team found the Hagahai to be suffering from endemic diseases, as well as an assortment of outside diseases that many Hagahai had recently contracted. Jenkins and the IMR were concerned over low birth rates and high disease mortality among the Hagahai, which was leading to a precipitous drop in their population.[7]

In 1985, and three times subsequently, Carol Jenkins applied for research support from the U.S. National Geographic Society (NGS) to conduct research on the Hagahai. NGS agreed to fund Jenkins' research - the initial project was titled "Cultural History and Adaptation of the Hagahai of the Western Schrader Mountains, Papua New Guinea". This first project was submitted to Papua New Guinea's Medical Research Advisory Committee and given ethical clearance.

In 1987, Jenkins returned to the United States to raise funds for her research, and in an interview published in the *Los Angeles Times*, recalled that relations with the Hagahai had been initially difficult; but had subsequently warmed up.[8] Jenkins reported to the scientific community that her intentions at the time were *"to monitor and promote improvement in [the Hagahai's] health status [and], hopefully, alter the course of their future and aid their adaptation to the inevitable modernization of their biology and culture."*[9]

In May, 1989, the sample that would eventually be patented first left the Hagahai. Blood was drawn from 24 Hagahai men and women and rushed to the IMR's facilities in Goroka. This was, however, not the first time that the Hagahai had been asked to give tissue samples. As early as 1987, Jenkins' research findings reported that the IMR had sent Hagahai cells to a lab in Australia for testing.[10] And each of the 24 people who gave blood in the 1989 instance had been previously determined through immunoblot testing by the IMR to be infected with a retrovirus called HTLV-1 that the researchers sought. Once the blood arrived at the IMR, thymus lymphocytes ("T-cells") were separated from each of the blood samples and maintained in a life-sustaining culture.

At an unknown date following preparation of the samples by IMR technicians (but probably in mid-1989), the Hagahai's blood was flown to the U.S. National Institutes of Health's (NIH) labs outside of Washington, DC, where NIH scientists began to investigate the Hagahai's cells and the HTLV-1 virus they contain. Research confirmed that the retrovirus carried by the Hagahai was unique and potentially valuable in diagnostic tests and vaccinations for leukemia-related diseases.

A decision to patent was taken by early April 1990 (less than a year after the blood was collected), and on August 24, 1990, a patent application was filed for a cell line from one of the Hagahai donors, a healthy 20 year old man. Why had NIH suddenly moved from simply studying the Hagahai's blood to wanting to patent it? NIH's "Employee Invention Report," filed by the research team on April 16, 1990 is illuminating: *"To this end, the establishment of a T-cell line persistently infected with an HTLV-1-related virus, derived from a healthy New Guinean, will facilitate testing in Melanesia, where high prevalences of HTLV-1 infection have been found.* ***It is also likely to have important application to testing populations elsewhere in the world, and the potential exists for its use in vaccine development"*** (emphasis added).[11]

In other words, NIH thought the Hagahai's cells were likely to be valuable not only in diagnosing cases of leukemia and related diseases; but could even be part of a cure. The economic value of just diagnostic tests for HTLV and related retroviruses is in the millions of dollars. Cambridge Biotech, a U.S. maker of HTLV tests, recently sold its diagnostics business to the French company bioMerieux for U.S. $6.5 million cash.[12] The value of therapeutic applications would likely be considerably higher.

One would suppose that prior to the patent application (or sooner) NIH would have checked with the Hagahai and the Papua New Guinea government to see if they approved of Hagahai cells becoming U.S. government property. But RAFI's findings from FOIA confirm that NIH's only documentation of Hagahai and PNG government consent to this exportation, research, and decision to patent human cells are the letter of ethical clearance for Jenkins' 1985 National Geographic study and a mysterious document from the IMR outlining oral informed consent procedures to be used by researchers. This latter document, however, arrived at NIH nearly 5 years after the blood samples, on April 21, 1994. This raises very unpleasant questions about NIH officials possibly "manufacturing prior informed consent" almost four years after the first patent application on Hagahai cells was filed on August 24, 1990.

NIH has no documentation that the Papua New Guinea government or the Hagahai were ever consulted about the patent application.

The 1994 arrival of the IMR's informed consent guidelines at NIH corresponds to the period when Dr. Stephen Finley of NIH was preparing a "historical review of the Papua New Guinea patent application" for high-ranking NIH officials under pressure from governments, NGOs, and the press to explain why NIH was trying to patent pieces of indigenous people. Even now, two years later, NIH claims that this report contains confidential "trade secret and commercial or financial" information and refuses to release it and related documents to the public (see "Solomon Islands", pg. 4).

As NIH's lawyers steered the patent application through the bureaucracy of the U.S. Patent and Trademark Office (PTO), a "Technology Development Coordinator" at NIH noticed that Carol Jenkins, one of the five "inventors", was not employed by the U.S. government. This posed potential problems with ownership of the rights to the "invention". The others listed were all NIH researchers who, as part of NIH's work contract, had made prior arrangements to assign their rights to the government.

However Jenkins' case was different. NIH responded by faxing Jenkins personally and requesting clarification of the interest of the PNG government in the "invention". Jenkins responded on September 4, 1990 with a handwritten note reading *"My employer at the time of invention (and now also) is the Papua New Guinea Institute of Medical Research, a statutory body of the national government. My employ[ment] agreement is silent about assigning patent rights.* ***I am not expected to assign rights to PN Government according to the Institute's Director, Dr M Alpers."***[13] (emphasis added).

The issue was thus settled, or so it seemed. Three and a half years later, the Ambassador of the Solomon Islands to the U.S. wrote to various U.S. government officials protesting the fact that NIH had filed for patent on cell lines of a Solomon Islands citizen. As part of the U.S. government's response, the Ambassador was sent a copy of an internal NIH memorandum prepared by Dr. Finley, which characterized the PNG patent rights situation as follows: *"in a related patent case involving Papua New Guinea, the government elected not to retain their patent rights but instead allowed the inventor to retain their individual rights."*[14]

This is a less than forthcoming characterization of events, considering the only documentation on file at NIH was Carol Jenkins' fax and the ethical clearance issued for her National Geographic research. In fact, NIH has no documentation that the Papua New Guinea government or the Hagahai were ever consulted about the patent.

A Conspicuous Silence

On October 4, 1995, RAFI issued a press release attacking the patent and pointing out the relationship it has to the Human Genome Diversity Project (HGDP), a worldwide project to collect indigenous peoples' cells (see *RAFI Communiqué*, May 1993).

RAFI's release received quick attention from the press, as well as interested academics and former U.S. government officials who wished to defend the patent. A heated debate ensued on the topic,[15] and in particular the patent's implications for the HGDP. Conspicuously silent through it all was the U.S. government. Even the *New York Times*, *Science*, and the *Economist* could not find a government official to comment on the case.

SOLOMON ISLANDS: NIH STILL MAKING INTELLECTUAL PROPERTY CLAIMS

The same NIH research team that has obtained a patent on the Hagahai cells has also applied for a patent on cells from people from the Solomon Islands. Following diplomatic and NGO protests at the Conference of the Parties to the Convention on Biological Diversity in Jakarta in November 1995, U.S. Department of State spokesman John Matuzak read a statement to diplomats and NGOs indicating that the application had been withdrawn and that the U.S. government had no intention of pursuing any claims over the Solomon Islanders' biological materials. Matuzak echoed statements made in 1994 by Jonathan Friedlaender, an official of the U.S. National Science Foundation.

Yet no proof of the truth of these statements has been produced and important questions remain. Despite repeated requests, NIH has refused to release copies of the official documents that must be filed with the PTO in order for the patent application to be withdrawn. Given the track record of misstatements by government officials on the issue, RAFI is obliged to continue to consider the application valid until proof to the contrary is received.

Most importantly, on April 26, 1996, RAFI received notification from NIH that it would not release information about the Solomon Islands patent application because it contains "trade secrets and commercial or financial information". Directly contradicting statements made by the U.S. government to diplomats, NIH is still claiming that the Solomon Islands cell lines are private property of the U.S. government, and that divulging information about them will violate trade secrets.

Has the application in fact been withdrawn? No proof exists. Does the U.S. intend to try to patent the Solomon Islands cell lines in the future? Indications are strong that they might. We will keep a close eye on developments regarding these cell lines and report on them in future editions of *RAFI Communiqué*.

PNG AND THE HAGAHAI: A NEW U.S. PROTECTORATE?

Finally, in November at the Conference of the Parties to the CBD in Jakarta, a U.S. Department of State official offered the first public commentary by the U.S. government on the patent. The official, reading from a document prepared by NIH, claimed that the decision to patent the Hagahai cells was only taken "at the request"

Despite public statements by the U.S. Department of State that the PNG patent was only pursued at the Hagahai's request, FOIA findings have revealed that *"at no time did NIH investigators have direct interactions with the Hagahai"*, and *"NIH files do not contain any informed consent agreements."*

of persons in Papua New Guinea (he did not elaborate about who) and only after clear informed consent of the Hagahai had been established. Additionally, the official claimed, the U.S. government's primary motive in patenting the cells had been to "protect" the Hagahai from commercial exploitation by others, and that "50% of royalties" from the patent would go to the Hagahai. Paradoxically, the official also stated that the patent would likely have little commercial value.

The Papua New Guinea patent, so the official implied, appears to be viewed by some parts of the U.S. government as a bizarre new form of foreign aid. The costs of obtaining and then maintaining the patent over its' lifetime will likely amount to nearly a thousand dollars for each of the fewer than 400 Hagahai. Observers, wondered aloud that if the U.S. government was so intent upon helping, would the Hagahai rather have received cash instead of an expensive patent on their "immortalized" cells?

PATENT BLATHER

Defenders of the Papua New Guinea patent have made confusing public statements and erroneous commentary on the text of NIH's patent. To set the story straight, we'll review two of the most often repeated comments and clarify the facts.

With regard to the issue of sharing benefits with the Hagahai themselves, the former director of physical anthropology programs at the U.S. government's National Science Foundation stated that *"the patent application specifies that... 50% of any potential profit would go to the Hagahai themselves"*. In fact, United States patent applications make no provision (or allowance) for benefit sharing arrangements as part of the patent text. Even if some wording providing for benefit sharing were in the patent text (and it is not), it would not represent a binding commitment. A patent is a patent, and not a contract. Instead, patents simply include the name(s) of the "inventor(s)" and, if applicable, an "assignee" for the patent rights, most often the institution or company for which the inventor(s) work. Financial arrangements for profits from the patent are separate and made at the discretion of the assignee, who is sole owner of the patent. In the case of the Hagahai patent, the sole assignee is the U.S. government. The contention that an arrangement to benefit the Hagahai themselves is built into the patent is simply false.

Along similar lines, the director of the IMR in Papua New Guinea has repeatedly said publicly that mentioning the Hagahai in the patent ensures *"they would benefit if in the remote future some commercial development arose from this discovery"*.[16] Mentioning a population in a patent, the director claims, provides legal standing for the mentioned group to obtain profits from the patent. A recent U.S. patent on a gene linked to Alzheimer's and Parkinson's disease (U.S. 5,494,794) mentions indigenous people from North America, Senegal, Tibet, New Guinea, and the Amazon Basin, as well as 248 Caucasian people and 699 persons *"from various ethnic groups"*, in addition to blanket coverage of *"Californians and Georgians, British, Finnish, Italians, Jews, Arabs and Hindus"* and other groups. Following the director's logic, the patent owners had better prepare for complex procedure to deliver benefits to the nearly one billion people mentioned in the patent. But, in reality, mere mention of a group of people or corporation in a patent description has absolutely nothing to do with the distribution of a patent's benefits.

While it was probably news to Papua New Guineans, and the Hagahai in particular, that they were a new U.S. protectorate, in fact NIH, by its own admission, has absolutely no files that document a single request for patenting from Papua New Guinea. The only person in Papua New Guinea with which NIH had written contact was U.S. citizen Carol Jenkins. In response to RAFI's FOIA request, the lead NIH scientist on the patent, Dr. Richard Yanagihara, stated *"at no time did NIH investigators have direct interactions with the Hagahai"*,[17] and NIH's FOIA office confirms that *"NIH files do not contain any informed consent agreements."*[18]

A Startling Footnote to the PNG and Solomon Islands Cases

In April, 1996, Dr. Carleton Gajdusek, head of the NIH laboratory that obtained the PNG patent, an "inventor" in the Solomon Islands claim, and Nobel laureate, was arrested by the FBI and police in the U.S. on charges involving the sexual abuse of children who lived at his home. Over his career, Gajdusek had brought at least 54 children from Micronesia and Papua New Guinea to the United States, where they lived in the researcher's house and attended school at Gajdusek's expense.[19] Police searched Gajdusek's offices at NIH in Bethesda, and another office at an NIH facility in Fort Detrick, Maryland. Although police had suspected Gajdusek since 1989, previous investigations had been inconclusive, and it was not until a college age former ward of Gajdusek stepped forward that police had the necessary evidence to make the arrest.

According to press reports, Gajdusek used NIH stationery in letters to the U.S. Immigration and Naturalization Service requesting entry visas for the children, who had the approval of their parents to live with Gajdusek.[20] Dr. Gajdusek, through his lawyer and friends, has strongly claimed that he is innocent of the charges. Since Gajdusek's arrest, one of his former wards has come to Gajdusek's defense, while at least one other has made further accusations of sexual abuse.[21] The case has yet to go to court.

"50% of the Royalties" go to the Hagahai?

Defenders of the patent, both scientists and U.S. government officials, have repeatedly said that the Hagahai will receive 50% of the royalties from any money made from the patent, and that an agreement exists with the Hagahai to this effect. But despite numerous oral, written, and legal requests to the U.S. government and other persons involved in the patent for copies of this document to be made public, nobody involved with the patent has produced a copy, or any record of an oral agreement.

There are many pertinent questions regarding this agreement, first and foremost at this point - does it actually exist at all? Presuming that it does, what is this 50%? 50% of NIH's proceeds? 50% of Dr. Jenkins' portion of the royalties? 50% of the royalties after NIH and/or IMR's costs are subtracted? Are the Hagahai aware of the agreement? And, if so, are they aware that NIH has repeatedly said that it is very unlikely that any money will result?

Sharing the "Wealth"

Indigenous Peoples' Tissue Collected and Exchanged in Large Amounts by Various Medical Institutions

In April, 1996, RAFI was told by NIH that it intended to withhold information regarding the Solomon Islands cell lines and the Papua New Guinea patent on grounds of trade secrets, an indication that more intellectual property claims on indigenous peoples cell lines are likely. At the same time RAFI met with Colombian peoples' organizations and NGOs who were concerned that indigenous peoples' and Afro-Colombians' blood collected in Colombia was being exchanged among institutions involved in patenting in the U.S.

Ascertaining what cell lines NIH has and with whom it is sharing them takes on high importance since NIH has asserted that it may patent more cell lines. Communities whose cell lines are held by NIH have sound reason to be concerned that their cells may be patented.

The dozens of communities whose blood is held by NIH have sound reason to be concerned that their cells may be patented.

To investigate these questions, RAFI began an inquiry into the policy controls regarding NIH's obtention and sharing of human tissue samples with other institutions. RAFI also ascertained whether or not Colombian samples were being held by NIH. In part spurred by the attention given NIH facilities at Fort Detrick following Gajdusek's arrest, RAFI also investigated NIH's sharing of biomaterials with the U.S. military. On all counts, the investigation has revealed important and troubling new information.

Colombian Cells at NIH and Elsewhere

RAFI's investigation quickly revealed that NIH not only has Colombian human tissue samples; but has an enormous number of them, including blood samples from at least 27 groups of *"healthy Colombian Indians from... culturally distinct tribes distributed in 12 political departments (or states) and occupying markedly varying terrain."*[22]

The most recent figures available indicate that NIH has used at least 2,305 blood samples of Colombian people in its research, which were collected between 1987 and 1992. Of these, 77% (1,773) are samples from indigenous people. Of the remainder, about 15% (338) are from Afro-Colombian communities on the Pacific coast and 8% (193) are from *mestizo* (persons with both indigenous and European ancestry) communities.

It is unclear how many of the Colombian samples at NIH have been "immortalized" into permanent cell lines, although judging by their relevance to ongoing HTLV

research, it is quite likely that many have. Most of these samples have been used by the National Institute of Neurological Disorders and Stroke (NINDS), the NIH unit that patented the Hagahai cells. Indeed, Richard Yanagihara and Carleton Gajdusek are both authors of the NIH studies on the Colombian cells.

Other research has revealed that the Atlanta-based Centers for Disease Control (CDC), a U.S. government institution which filed and then, under pressure, withdrew a patent application on a human cell line from the Guaymi people in Panama (see *RAFI Communiqué*, Jan/Feb 1994), has additional Colombian material from both indigenous and Afro-Colombian communities (see map, page 12).

Colombian indigenous peoples' tissues used at either CDC or NIH include samples from the following indigenous peoples:[23]

- Achagua (NIH)
- Barasana (NIH)
- Chimila (NIH)
- Cuaiquer (NIH)
- Cuna (NIH)
- Embera (NIH)
- Guanano (NIH)
- Guayabero (NIH)
- Motilon (NIH)
- Piapoco (NIH)
- Pisamira (NIH)
- Tucano (NIH)
- Waunana (NIH)
- Wiwa (NIH)
- Arhuaco (NIH)
- Cenu (NIH)
- Coreguaje (NIH)
- Cubeo (NIH)
- Desana (NIH)
- Guahibo (NIH)
- Guane (NIH)
- Kogi (NIH)
- Paez (NIH)
- Piratapuyo (NIH)
- Tikuna (CDC+NIH)
- Tunebo (NIH)
- Wayuu (CDC+NIH)

NIH says that most of the blood samples it has used were collected by the "Great Human Expedition" (*La Gran Expedición Humana*), an effort made by Colombian universities to document Colombia's indigenous people and Afro-Colombian communities. The primary research group for health aspects of the expedition was the Genetics Institute of the Universidad Javeriana in Bogotá. The Genetics Institute is also a lead organization in the implementation of the Human Genome Diversity Project (HGDP) in Colombia.

The expedition received support from a variety of Colombian institutions, as well as several multinational life industry corporations, including Hoechst, Parke-Davis, and Pfizer.[24]

Javeriana and other institutions participating in the expedition have been criticized by Colombian indigenous peoples' organizations and NGOs for their collection methods, as well as for being unwilling to release information about where it had exported the indigenous peoples' blood it had collected. British filmmakers have documented that Javeriana does not obtain informed consent in blood collection and has provided samples to researchers at a California (USA) subsidiary of biotech giant Hoffman LaRoche.[25]

The fact that HGDP's lead scientists in Colombia have, over a period of years, provided thousands of indigenous peoples' blood samples to the only lab in the world that has ever patented an indigenous person's cell line, is a matter of considerable concern.

In 1992, NIH and Javeriana researchers collaborated on an article which detailed that two specific types of HTLV had been simultaneously confirmed for the first time in an indigenous population in Latin America, in their words *"the present study clearly targets the Wayuu Indians as a candidate population in which to conduct in-depth investigations..."* [26]

The article parallels NIH and IMR's article from 1990, in which they "revealed" the discovery of a new variant of HTLV in the Hagahai's cells. Following the logic used by NIH for the Hagahai patent, in which discovery of a new naturally-occurring phenomenon is patentable, the cells from the new research may be considered an "invention" by NIH. RAFI has not found documentation of any attempt to patent them so far , but such documents are normally secret until the patent is issued. The situation signals the possibility that NIH will try to patent Colombian cell line(s).

In addition to the blood samples at NIH and CDC, RAFI research has confirmed that a variety of other researchers in the U.S. and Japan have been using Colombian human tissues:

- Harvard University (USA) has at least three cell lines from Tumaco;[27]
- Kyoto University (Japan) has an undisclosed number of samples of "native inhabitants" of Colombia;[28]
- Cornell University (USA) reports that it is sequencing part of the HTLV strain found in blood samples from the Wayuu people in Colombia;[29]
- Kyushu University (Japan) has cell lines from "areas of Colombia" where HTLV infection is "endemic";[30]
- Johns Hopkins University (USA) has 1,077 blood samples from Tumaco;[31]
- Texas Technological University (USA) has 50 samples from Tumaco.[32]

More Human Blood Samples Circulating...

RAFI's research on Colombia also revealed many other instances of indigenous peoples' blood being used by researchers in the United States and Japan. While not all these human samples may be candidates for patenting, and - indeed - some of the institutions holding these samples may not want to patent them, the degree to which indigenous peoples' cells are being transferred between research institutions without indigenous peoples' knowledge or approval is disturbing. The following are some examples which represent only a small portion of the traffic in indigenous peoples' blood samples:

- Yale University (USA) has 703 blood samples from the Kayapo people of Brazil, on which it is conducting HTLV-related research.[33]

- The National Cancer Institute (NCI) says that it has blood samples from "adults in 13 isolated South and Central American Indian tribes", and specifically mentions the Kayapo and Kraho peoples from Brazil.[34]
- NCI also says that it is working with human tissue samples from China, the French West Indies, Haiti, Mauritania, Guinea-Bissau, Ivory Coast, Central African Republic, Zaire, French Guyana, Peru, Solomon Islands, and Papua New Guinea.[35] What portion of these are from indigenous people is unclear.
- CDC, in addition to the previous work mentioned in this *RAFI Communiqué*, confirms that it has used blood samples in HTLV research from Brazil, Ethiopia, Indonesia, Jamaica, Japan, Mexico, Panama, Peru, and Somalia.[36] What portion of these are from indigenous people is unclear.
- Kyoto University, in addition to previously mentioned work, is using blood samples from the Ainu people (Japan), Gabon, Ghana, and India.[37]
- Kyushu University, in addition to previously mentioned work, has human tissue samples from Jamaica and Chile.[38]

Parallel Initiatives by the U.S. Navy

The U.S. Navy, through medical research units in Jakarta, Indonesia and Lima, Peru also has its own program to collect blood samples for HTLV research. Following NIH's report on its research on the Hagahai cell lines, U.S. Navy researchers traveled to Irian Jaya (West Papua), in order to collect their own HTLV samples from indigenous people. They chose to sample 165 members of the Ngalum people, an isolated group in the Jayawijaya Mountains along the Papua New Guinea/Indonesia border.[39] The Ngalum are estimated to number 18,000. About half the Ngalum live in Indonesia, and about half in Papua New Guinea.[40]

The U. S. Navy's research unit in Lima, Peru has also drawn blood samples for HTLV research there. There, the U.S. Navy has taken blood samples from *"395 prostitutes from Callao, Peru (the port city of Lima), 72 prostitutes from Iquitos, Peru (another port city on the Amazon River), and 510 prenatal clinic patients from Lima."*[41]

The Naval Medical Research Institute, next door to NIH's central facility near Washington, has also obtained blood samples from Palawan, Philippines, although it is unclear if the Navy itself drew them, or if they were obtained from other researchers.[42]

Policy and Control of the Flow of Human Samples

RAFI's Investigation of Policy at NIH

With the large number of samples of indigenous peoples' tissues being used in Northern laboratories, the terms and policy under which such samples are transferred is an important question. RAFI investigated policy on these matters at NIH because it appears to have the world's largest collections of indigenous peoples tissues, and is the only group so far to patent them.

RAFI's investigation focused on NINDS and the NCI, two units of NIH with large collections. Much of NINDS and NCI's research on human tissues takes place not at NIH's central facility at Bethesda near Washington, DC; but rather in facilities at Fort Detrick, Maryland. Prior to 1972, when the U.S. officially ended offensive biological and chemical weapons research, the Fort Detrick facility was the headquarters of the U.S. military's biological weapons research units.

Following 1972, the U.S. military partially vacated the Fort Detrick facility and NIH moved in. Fort Detrick is now shared by NCI, NINDS, several U.S. Army medical groups, and a medical agency of the Defense Intelligence Agency (DIA).

Army units at Fort Detrick include the U.S. Army's Medical Research Institute of Infectious Diseases (AMRIID), an Army group researching counter-measures to biological warfare agents,[43] which houses the U.S. Army's collection of biohazardous materials in one of the world's most secure facilities. Behind the extensive biosecurity measures is a library of samples of extremely virulent viruses such as Ebola that are subjects of ongoing research by scientists worldwide.

DIA researchers at Fort Detrick belong to the Armed Forces Medical Intelligence Center (AFMIC), which *"facilitate[s] the coordination of high-quality intelligence to both the policymaker and warfighter... under the Department of Defense Intelligence Production Program."* AFMIC does this by focusing on foreign countries' medical capabilities, epidemiology, life sciences, and technology. In AMFIC's own words, it *"assesses foreign basic and applied biomedical and biotechnological developments of military medical importance," and "produces current intelligence focusing on foreign military and civilian medical capabilities, public health conditions and infrastructure... and the impact of HIV/AIDS on military and general populations."*[44]

The offices and biological collections of NINDS, as well as those of numerous NCI researchers are at Fort Detrick. In addition, Fort Detrick houses the collections of NCI's Developmental Therapeutics Program (DTP), a leader in the collection and pharmacological analysis of plants and other biological specimens from throughout the globe.

Both the Army and NIH facilities at Fort Detrick are managed by a private company under a government contract. The company, Science Applications International Corporation (SAIC), is a San Diego-based, privately-held firm which specializes in high-tech work for the U.S. Department of Defense and foreign intelligence agencies.[45] SAIC's board includes, or has recently included, the current and former Secretaries of Defense and Directors of the Central Intelligence Agency (CIA), among other people intimately linked to the U.S. military and foreign intelligence operations.[46]

SAIC is also working with InCyte, a California-based gene sequencing company with thousands of patent applications on human materials (See *RAFI Communiqué*, May/June 1994), to develop the "next generation" of high-speed gene sequencing equipment.[47] SAIC's 1,400 member staff at Fort Detrick performs a variety of support work for both the Army and NIH, from basic clerical work to the maintenance of human cell line cultures and the management and transfer of biomaterials to other institutions.[48]

In the course of our research, RAFI interviewed representatives of NIH, SAIC, AMRIID, and the U.S. Army Medical Research and Materiel Command (USAMRMC) to inquire about the sharing of NIH's extensive biomaterials collection not only with U.S. Army researchers; but with other scientists in general. Given the highly sensitive nature of human materials from indigenous people and plant samples collected for "medical research" by NIH, RAFI sought to ascertain what NIH controls were in place to prevent such materials being used by the military. We have discovered that there are none.

RAFI sought to ascertain what controls were in place to prevent NIH's human and plant samples from being used by the military. We have discovered that there are none.

While unwilling to cite specific examples, officials from SAIC, AMRIID, USAMRMC, and NIH all confirm that any NIH-held materials may be transferred to the Army (or anyone else, including corporations), subject to the approval of the lead scientist of the lab in which they are held. Officials also confirm that materials are routinely transferred between the institutions.[49] The SAIC representative, who is Fort Detrick's expert on material transfers said that there was no restriction on such transfers and no reason (or policy) why they would not take place.

RAFI has documented that U.S. military-collected samples are almost certainly being shared with NIH and CDC researchers. CDC, writing with persons from Walter Reed Army Hospital and two biotechnology companies from California, acknowledge working with blood specimens from Peruvian prostitutes - almost certainly the same ones collected by the U.S. Navy in Lima and Iquitos.[50]

When NIH transfers samples to outside groups, NIH says that they are usually - but not always - released with a materials transfer agreement (MTA) that prohibits their use for commercial purposes.[51] None of the representatives RAFI interviewed remembered any MTA provisions regarding military purposes. With or without MTAs, cell line transfers between the military and NIH are troubling. In contrast to SAIC and NIH's statements about transfers, the U.S. Army reports that it regularly receives cell lines from outside researchers without any MTA (although the official would not elaborate on specific examples).[52]

Potential donors of human tissue (and plant samples) should take this situation into consideration in their decision to participate or not participate in research. At present, there is no guarantee that samples donated to NIH will not be used for military purposes. The complete absence of U.S. government policy in this area underscores the lack of attention paid to serious ethical issues regarding the obtention and distribution of human (and other) biological samples.

Conclusion

The collection, handling, and exchange of human tissue samples - especially across international borders - is conducted by an unacceptable *ad hoc* approach. The transnational traffic in human tissue samples, especially those of indigenous people, appears to be growing sharply. The U.S. government has patented the cell line of a Papua New Guinean indigenous person with no documentation of either his informed consent or approval of the Papua New Guinea government. While intergovernmental organizations, medical and bioethics protocols continue to exclude concerns about the export, immortalization, commercialization, and patenting, human biological samples are being exchanged and used in ways that tissue donors are not aware of, nor would likely endorse.

RAFI has no evidence that U.S. military researchers have used foreign human cell lines (or internationally-procured plant samples) for offensive biological warfare research; but no policies or protocols prevent civilian medical researchers from sharing biomaterials with military researchers. The U.S. military does, however, acknowledge that samples obtained from NIH are used in defensive programs. It appears that human tissues also flow from military researchers to NIH. This is a serious problem that countries participating in NIH and CDC-sponsored medical research programs should consider.

Actions that can be taken by governments and NGOs to develop more effective controls on the patenting and exchange of human tissues include:

- Addressing the issue at the World Health Assembly of the World Health Organisation (WHO) in Geneva from 20-25 May, 1996 and in future WHO meetings.
- Bringing the issues to the U.N. Human Rights Subcommission on Prevention of Discrimination and Protection of Minorities, Working Group on Indigenous Populations session, 29 July - 2 August, 1996 in Geneva.
- At the September meeting of the U.N. Convention on Biological Diversity's Subsidiary Body on Scientific, Technical, and Technological Advice (SUBSTTA) in Montreal, the relevance of human tissue issues could be pointed out to the CBD.
- The Fourth Review Conference of the Biological Weapons Convention in Geneva in November 1996,

issues pertaining to military uses of human samples can be addressed.

At these bodies, the following points can be made:

- The HGDP should be investigated by the U.N. Human Rights Commission, its files and membership should be fully disclosed, and HGDP should place itself under U.N. supervision. Under no circumstances should the HGDP undertake collections until binding international protocols are in place as summarized below.
- Strict, legally-binding international commitments must be established to ensure that biomaterials collected for the purpose of medical research are inaccessible to military researchers in any way associated with chemical or biological warfare research.
- Prior informed consent is required from both the subjects of medical research and their communities or governments before materials or information arising from the research can be commercialized in any form.
- There should be no further collection or exchange of human tissue until the above conditions are assured.
- People and governments should not make information or material available to the United States until appropriate remedies are made to current policy and the U.S. can guarantee full compliance with the terms set above.

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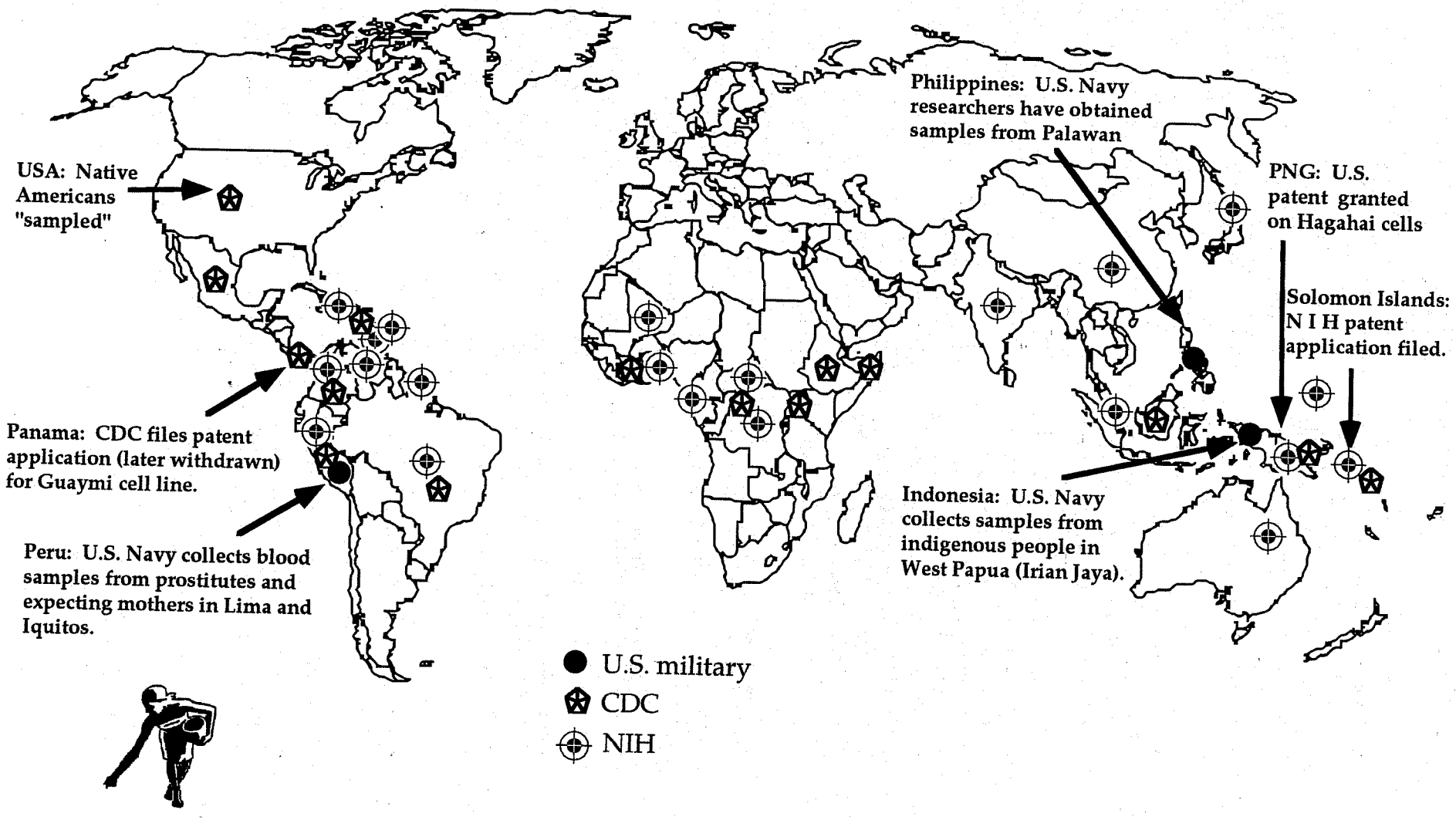
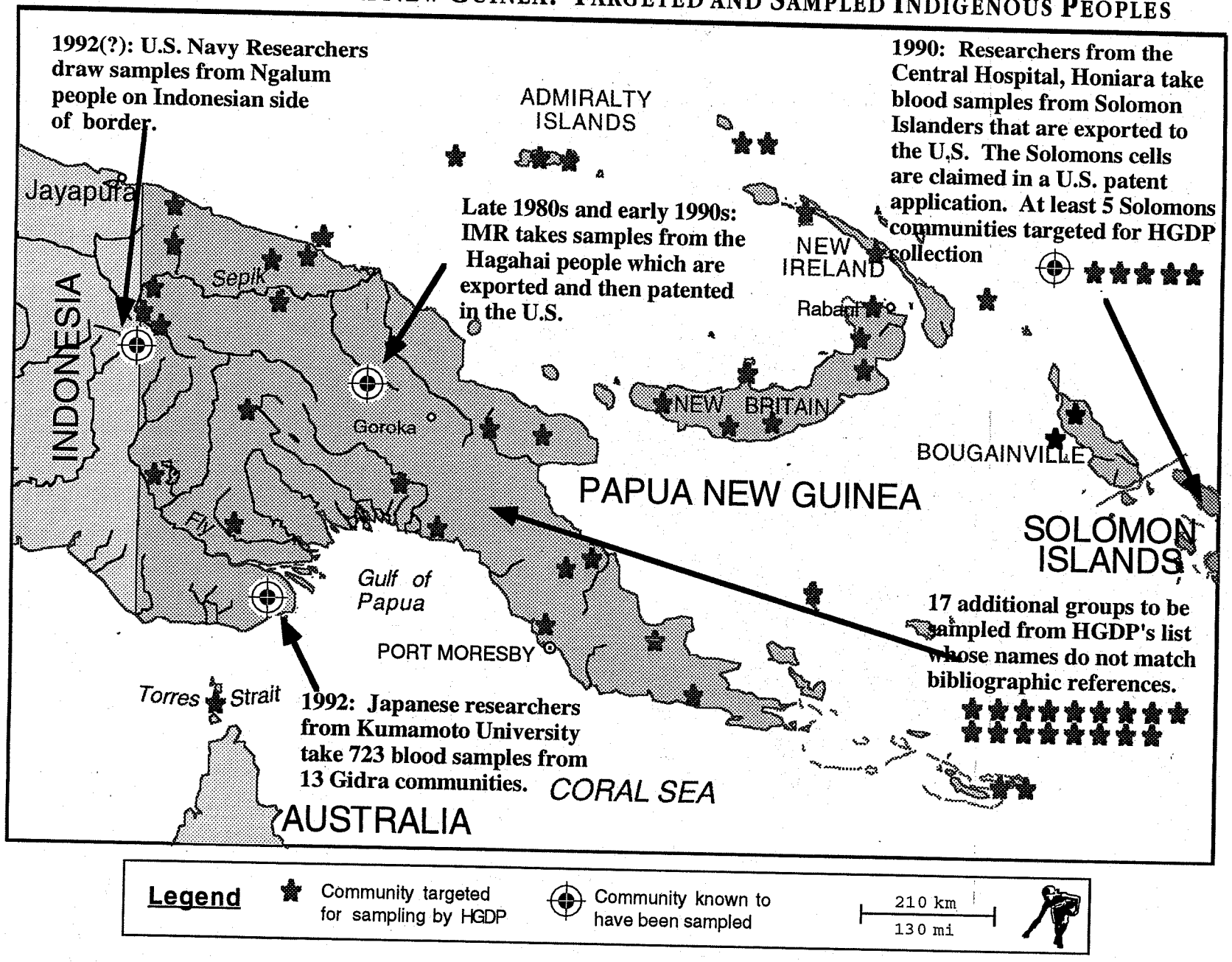
[1] Thomas, S.M. et al. "Ownership of the Human Genome", in Nature, 4 April 1996, p. 388.
[2] Shrine, Jim. "Sequana Files for IPO, Signs Potential $70 Million Asthma Deal", BioWorld Today, 15 June 1995, p. 1.
[3] Canada NewsWire, 23 January 1995.
[4] U.S. Patent 5,494,794, "Detection of mitochondrial DNA mutations associated with Alzheimer's disease and Parkinson's disease", 27 February 1996.
[5] "US slaps patent on tribesman's DNA", The Independent (London), 19 November 1995, pg. 1.
[6] Jenkins, Carol L. "Medical Anthropology in the Western Schrader Range, Papua New Guinea", in National Geographic Research 3(4):412-430 (1987), p. 413.
[7] Los Angeles Times, 27 December 1987, "Disease Threatens Survival of Remote, Stone Age Folk".
[8] Los Angeles Times, 27 December 1987.
[9] Jenkins, Carol L., p. 428.
[10] Jenkins, Carol L., p. 428.
[11] "Employee Invention Report" (no number assigned), filed at NIH, April 1990 (Obtained by RAFI under FOIA).
[12] Marketletter, "Cambridge Biotech To Sell Retroviral Diagnostic Business", 15 April 1996.
[13] Fax letter from Carol Jenkins, IMR to Carole Kirby, NIH 9 April 1990 (obtained by RAFI under FOIA).
[14] From memo by Dr. Stephen Finley to Acting Director, National Institute of Neurological Disorders and Stroke (NINDS), 9 February 1994.
[15] See *http:// www.charm.net/~rafi/pp.html* on the internet for the debate and related information.
[16] Uni Tavur (Port Moresby), 23 February 1996.
[17] Quoted in letter from Joanne Belk, Acting Freedom of Information Officer, NIH to RAFI, 26 April 1996.
[18] From letter from Eli Landy, Freedom of Information Legal Specialist, NIH to RAFI, 22 March 1996.
[19] Gillis, Justin, "NIH Scientist Charged With Abusing Teen; Nobel Laureate Has Brought Dozens of Boys to Md. From Overseas", Washington Post, 5 April 1996, pg. A-1.
[20] Higham, Scott and Marcia Myers, "Transport of children is probed; Accused scientist brought dozens into this country", Baltimore Sun, 6 April 1996, pg. A-1.
[21] Wagner, Arlo, "Nobel Prize winner indicted again on charges of child sexual abuse; Frederick County grand jury bases decision on FBI accounts", Washington Times, 27 April 1996, p A-9 and Gillis, Justin, "A Magical or Miserable Childhood?; Accuser's Story Clashes With Fond Memories of Gajdusek as Benefactor of Pacific Island Boys" Washington Post, 27 April 1996, p. A-1.
[22] Dueñas-Barajas, et al. "Human Retroviruses in Amerindians of Colombia", Am. J. Trop. Med. Hyg. 49 (6), 1993, pp. 657-58.
[23] Composite data from Am J. Trop. Med. Hyg. 1993 Dec; 49(6): 657-63, AIDS Res. Hum. Retroviruses 1992 Nov; 8(11): 1851-5, Virus Genes 1995; 10(2): 153-62, and U.S. Patent 5,494,794 Feb. 27, 1996, "Detection of mitochondrial DNA mutations associated with Alzheimer's disease and Parkinson's disease".
[24] Bernal Villega, Jaime, et al. *"Terrenos de la Gran Expedición Humana"*, vol 3., Bogotá: Universidad Javeriana, 1994, p. 7. Other groups which supported the work include: Knoll Labs, Allergan Labs, Specia Labs, Sidney-Ross Labs, and Synthesis Labs.
[25] See "The Gene Hunters", Channel Four, London, 1995.
[26] AIDS Res. Hum. Retroviruses 1992; (8): 1851-55.
[27] Am. J. Trop. Med. Hyg. 1995 Feb; 52(2): 155-8.
[28] Proc. Natl. Acad. Sci. USA 1994 Feb 1; 91(3): 1124-7.
[29] Jpn. J. Cancer Res. 1993 Dec; 84(12): 1215-8.
[30] Neurology 1992 Nov; 42(11): 2210-2.
[31] Ann. Neurol. 1988; 23 Suppl: S151-5.
[32] J Neurol. Sci. 1988 Oct; 87(1): 121-38.
[33] AIDS Res. Hum. Retroviruses 1994 Sep; 10(9): 1165-71.
[34] J. Infect. Dis. 1992 Jul; 166(1): 100-7.
[35] J. Virol. 1992 Apr; 66(4): 2288-95.
[36] J. Infect. Dis. 1992 Nov; 166(5): 1160-3 and Clin. Diagn. Lab. Immunol. 1994 Jan: 1(1): 5-10.
[37] Proc. Natl. Acad. Sci. USA 1994 Feb 1; 91(3): 1124-7.
[38] Neurology 1992 Nov; 42(11): 2210-2.
[39] Am. J. Trop. Med. Hyg. 1993 Feb; 48(2): 230-6.
[40] Ethnologue, Dallas: SIL, 1992, p. 856.
[41] J. Med. Virol. 1992 Sep; 38(1): 44-8.
[42] J. Med. Virol. 1995 Apr; 45(4): 469-74.
[43] Critics of the 1972 Biological Weapons Conventions have pointed out that research like that done at Ft. Detrick "is difficult to distinguish... from that intended to produce offensive weapons because many of the same procedures are required for both... to create vaccines that could be used to defend against an attack with biological weapons, the warfare agent itself must be produced" (CRG's Genewatch, July 1991).
[44] "Defense Intelligence Agency (DIA) Armed Forces Medical Intelligence Center (AFMIC)" (descriptive document on the DIA's internet site) URL: "http://www.dia.mil/nov95/003_11_95.html".
[45] Intelligence Newsletter, 4 April 1996, and San Diego Union-Tribune, 12 November 1995, p. A-22.
[46] San Diego Union-Tribune, 12 November 1995, p. A-22.
[47] PR Newswire, 29 February 1996.
[48] Telephone interviews with Jeff Derge, SAIC and Stephen Marquez, NCI, 9 May 1996 and SAIC Magazine, November 1995 (http://www.saic.com/corporate/magazine/article04.html).
[49] RAFI conducted telephone interviews with the following persons for this section: Chuck Daisey, Public Affairs Officer, USAMRMC, Fort Detrick; Jeff Derge, SAIC contract employee, Fort Detrick; Bob Hawley, Biosafety Office, USAMRIID, Fort Detrick; Stephen Marquez, Technology Development Office, NCI, Fort Detrick.
[50] J. Infect. Dis. 1992 Jul; 166(1): 100-7.
[51] Telephone interviews with Jeff Derge, SAIC and Stephen Marquez, NCI, 9 May 1996.
[52] Telephone interview with Chuck Daisey, USAMRMC, 16 May, 1996.

Collecting the World Over.... Human Tissue Samples Used by U.S. Government Institutions



DRAWING BLOOD IN PAPUA NEW GUINEA: TARGETED AND SAMPLED INDIGENOUS PEOPLES



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