The Havasu 'Baaja tribe and informed consent

Published Online
July 13, 2010
DOI:10.1016/S0140-6736(10)60818-5

The Havasu 'Baaja tribe, or as they are more generally referred to, the Havasupai, has about 650 members. This tiny band of Native Americans has won a momentous lawsuit that might demand rethinking about the way biological materials are obtained for use in scientific research.

In 1882, the US Government declared the tribe's Grand Canyon land to be a national park and the Havasupai were confined to a small area at the bottom of the canyon. After 100 years of wrangling, the Government restored 185 000 acres to the tribe but, by then, traditional hunting, fishing, and farming had long been replaced by tourism as the tribe's main means of earning a living. Along with the tourists and visitors came all manner of new non-native food and drinks. The Havasupai found themselves ravaged by type 2 diabetes.

In 1990 three scientists at Arizona State University started a research project to better understand the diabetes epidemic. This project was done with the support of the US National Institutes of Health, and with the approval of the University's institutional review board and of the seven-member council of the Havasupai tribe. The investigators took at least 400 blood samples from 180 tribal members to determine whether genetic factors might be putting some members of the tribe at risk of type 2 diabetes.

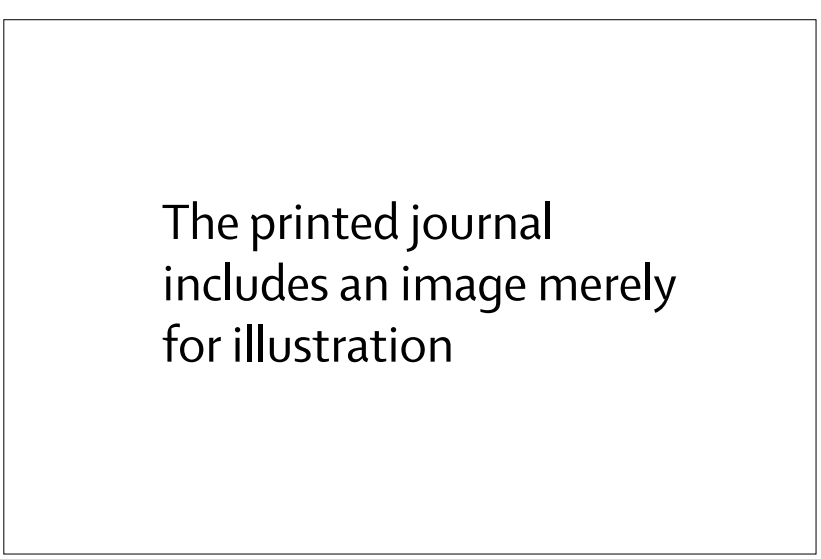
But the genetic studies revealed little about a proclivity to diabetes. By 1992, the researchers expanded their studies to include genetic and medical records analysis of inbreeding, schizophrenia, migration history, and genealogy—without the explicit consent of those who had supplied the original blood samples. More than a dozen papers were published on these topics.[1,2] It was only when a tribal member attended a talk at the Arizona State University about some of the non-diabetes work that the tribe became aware of the additional studies. They were angry and filed suit against the researchers, the institutional review board, and the University Regents.[3]

In April this year, the Arizona State University's Board of Regents agreed to pay US$700 000 to 41 of the tribe's members, return all blood samples, provide scholarships, and help build a new health clinic for the impoverished Havasupai. Although no liability was acknowledged, this settlement is hugely important because it means that research participants can be wronged when they are not fully and precisely informed about the way their DNA might be used.[3]

For many years the dominant belief for those interested in genetic studies has been to treat the people supplying tissue samples, genetic material, or genetic data as the subjects of research.[4] After decades of merely collecting tumours, placentae, and other body materials,[5] the research community around the world came to understand the need for informed consent. This right to consent has been extended to data generated from biological materials when linked to identified individuals.[4]

The mandate to obtain informed consent has created a host of ethical challenges.[4-7] It is not clear how or whether tissue collections assembled long before informed consent became the standard of practice can be accessed for research.[7] And until the Havasupai settlement, it was not clear whether biological materials collected for a specific research purpose could be used for other purposes without the reconsenting of individuals. Moreover, the issues generated by an ethical standard that sees tissue collection as requiring strict informed consent are not confined to biobanking.

The recent decision of a National Institutes of Health task force to place limits on the use of human embryonic stem-cell (hESC) lines also draws attention to the fact that the informed consent framework is highly



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Havasupai Indian performs a ceremony before news conference after the lawsuit

problematic. Unlike the limitations of George Bush's administration, which drew an arbitrary line between acceptable and unacceptable hESC lines on the basis of the date of their creation, the Obama policy is based on the documentation of full informed consent for the use of each embryo. However, written consents obtained in the past often specify a certain disease for which research on the derived hESCs will be used. The National Institutes of Health has taken a position that the informed consent framework seems to demand, by refusing to declare existing lines eligible for funding unless documented consent can be obtained. Moreover, this consent cannot limit research to a particular disease or condition.[8]

The complications with the existing informed consent framework are made clear in both the Havasupai settlement and the National Institutes of Health's policy for hESCs. Investigators must either know in what direction their research might lead, so that the donors can be informed about these prospects, or they must find and reconsent donors years or decades later, when new research opportunities present themselves.

The temptation will be to further refine and haggle over consent forms, but we think it is time to rethink the entire model for obtaining biological materials. In the field of transplantation, individuals are asked to donate their organs and tissues as gifts to the medical community.[9] Some are used in research, some in therapy. Once donated, all rights and control over the use of organs and tissues are foregone.

Could and should such a model be used in biobanking and other forms of tissue, cell, and gene collection? Why treat people as subjects when they are not involved in a serious way as the subjects of such research, and when their identities can be disassociated from their tissues? Why not, instead, ask individuals to make a gift to scientific research and avoid all the challenges that the informed consent framework creates? The Havasupai case suggests some hard ethical rethinking might be in order.

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We declare that we have no conflicts of interest.

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