

Native Hawaiian Preferences for Informed Consent and Disclosure of Results From Genetic Research

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Abstract—*Background.* Informed consent is generally waived when using anonymous stored specimens in research because individual harm is minimal; however, group harm may arise if specimens contain ethnic identifiers. *Methods.* We assessed preferences for informed consent and disclosure of results from genetic research through a survey (N = 429, 83.2% Native Hawaiian). *Results.* Native Hawaiians were more likely than non-Hawaiians to require informed consent for genetic research using personally identified (81% vs 77.8%), anonymous (40.9% vs 34.7%), and ethnically identified specimens (51.3% vs 33.3%). Most respondents wanted results reported to them (87.6%) and to their physicians (79.0%). *Conclusions.* Recognizing community preferences for informed consent and disclosure of research results may alleviate concerns about group harms inherent in genetic research. *J Cancer Educ.* 2006; 21(Suppl.):S47-S52.

Cancer research frequently involves genetic testing of stored biological specimens that were obtained during clinical care (eg, tumor biopsy) or previous research.¹⁻³ Such investigations increasingly involve specimens taken from members of minority groups such as the Native Hawaiians whose cancer health disparities and unique heritage are of interest to researchers.⁴ In many cases, guidelines for this type of research, including those set forth by the US federal government's "Common Rule" (Code of Federal Regulations §46.101) and the American Society of Human Genetics,⁵ do not require researchers to obtain informed consent when specimens are anonymous (ie, when specimens retain no personal identifiers because they were collected anonymously or were anonymized prior to inclusion in research) because it is believed that the potential for individual harm is minimal. However, the potential for group harm (eg, stigmatization, discrimination, loss of health insurance)^{1,4,6} remains because specimens generally retain

group identifiers, such as ethnicity, and genetic research on individuals within a population effectively subjects the entire group to share adverse consequences that may result from involvement in research.⁷

It has been suggested that the potential for group harm may be reduced by allowing the populations under study to have input into both the research development process and the interpretation of results.² Specifically, researchers who use stored biological specimens, especially those that contain ethnic identifiers, should consider the preferences of specific minority populations for informed consent as well as preferences for dissemination of research findings.

Previous research in this area is sparse but includes a survey of the Jewish population in the eastern United States that asked participants whether written informed consent should be required for the use of stored DNA samples in research on a variety of illnesses. Most respondents (60%-75%) believed that informed consent should be a requirement, and participants were significantly more likely to require consent for the use of DNA samples that had been obtained in a clinical setting as opposed to a research setting.²

Wendler and Emanuel⁸ surveyed a national sample of 504 older adults, 90% of whom were White, about their preferences for informed consent in nongenetic research. Wendler and Emanuel⁸ found that 67% of White respondents would want to be consented for use of personally identified samples obtained during clinical care, 26% for use of anonymous samples obtained during clinical care, 29% for use of personally identified samples obtained during previous research, and 11% for use of anonymous samples obtained during previous research. We applied Wendler and Emanuel's⁸ survey

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tool in Hawai'i and found that Native Hawaiians were more likely to require consent than the Whites in the national sample—about 78% of Native Hawaiians would want to be consented for the use of personally identified specimens and about 36% for use of anonymous specimens regardless of how they were obtained.⁹ Among participants from both the Native Hawaiian study and the national study, an overwhelming majority (82%-91%) would want access to research findings and would want their physicians to know the research results as well.^{8,9}

In this article, we present data on Native Hawaiian preferences for informed consent and dissemination of results from genetic research. We address the following research questions:

1. Do Native Hawaiians want to be consented for genetic research that uses stored biological specimens?
2. When conducting genetic research, for what types of specimens should informed consent be required (ie, personally identified, anonymous, ethnically identified)?
3. To whom should genetic research results be disclosed—to specimen donors? or to physicians?

MATERIALS AND METHODS

Study Population

Although our study was designed to target Native Hawaiians, our sampling frame included adults age 18 and older—both Native Hawaiian and non-Hawaiian—who were associated with the Native Hawaiian Health Care Systems (NHHCS), federally funded agencies that provide outreach, health education, and limited primary-care services to roughly 10000 Native Hawaiians across 6 islands (Hawai'i, Kaua'i, Lana'i, Maui, Moloka'i, and O'ahu), with the bulk of care provided by Native Hawaiian health professionals and outreach workers. We trained community outreach staff from each NHHCS venue to recruit participants and administer the survey in a face-to-face format. We obtained informed consent from each participant, and completed surveys were confidential. Each participant was given a small incentive (eg, a \$5 gift certificate for a local gas station or grocery store), and the NHHCS received \$10 for each completed survey. In all, surveys were completed by 429 individuals including 82 from the island of Hawai'i, 99 from the island of Kaua'i, 76 from the island of Maui, 87 from the island of Moloka'i, and 85 from the island of O'ahu.

Survey Development

Our survey was based on an instrument used by Wendler and Emanuel⁸ to assess preferences for informed consent in a national study but was expanded to include items pertaining to genetic research. Before data collection began, we pre-tested our survey with 15 key informants from the Native Hawaiian community to assure clarity and readability.

Before completing the survey, participants were asked to read a brief document providing background information on research that uses stored specimens. *Stored specimen* was defined as blood or tissue that was kept in a laboratory after it was initially taken from a person's body during surgery (for medical purposes) or during a research study (to learn more about medicine). The survey presented participants with a hypothetical scenario—"A researcher wants to use your 'stored specimen' for a genetic study, to study your genes"—and asked participants if informed consent should be required for the use of: (a) a personally identified specimen, (b) an anonymous specimen, and (c) an ethnically identified specimen. Participants were also asked if they would want to know the results of the research and if they would want their doctors to be told.

Statistical Analysis

We used SPSS Version 10.0 (SPSS Inc, Chicago, IL) to calculate the number and percentage of participants who would require informed consent for use of each type of stored specimen in genetic research. Because our sample included a subset of non-Hawaiian respondents, we were able to compare Native Hawaiian and non-Hawaiian responses to the survey items. We also used binary logistic regression to identify sociodemographic characteristics of the overall sample (ie, age, gender, ethnicity, marital status, education, employment status, income, religion and religiosity, surgical and cancer history, and past involvement with research and/or tissue research) that were associated with preferences for informed consent and dissemination of research results.

Approval

Prior to its inception, we proposed this project to the combined councils of *'Imi Hale*—Native Hawaiian Cancer Awareness, Research, and Training Network to solicit feedback and approval to proceed and to assure cultural appropriateness and cultural sensitivity. Once approved by the combined councils, we obtained approval from the NHHCS Institutional Review Board. We also reported findings from this study back to administrators of the NHHCS and incorporated their feedback into the interpretation of our results.

RESULTS

Table 1 presents sociodemographic characteristics of Native Hawaiians (n = 357), non-Hawaiians (n = 72), and all respondents (N = 429) in our sample. As shown, Native Hawaiians comprised 83.2% of the overall sample. Among the two thirds of Native Hawaiians who specified blood quantum, 72.3% were at least 50% Native Hawaiian. More than half of our sample was younger than age 50, with a mean age of 42.5 years. The majority of respondents (70.4%) were employed, with the median household income between \$25,000 and \$39,999, and over half of respondents (58.9%) had at least some college-level educa-

TABLE 1. Sociodemographics* of Native Hawaiians, Non-Hawaiians, and All Respondents Accrued to 'Imi Hale's Study Addressing Preferences for Informed Consent and Dissemination of Results From Genetic Research⁹

Sociodemographic	Native Hawaiian (n = 357)		Non-Hawaiian (n = 72)		Overall (N = 429)	
	N	%	N	%	N	%
Sex						
Male	95	26.6	23	32.4	118	27.5
Female	262	73.4	48	67.6	310	72.3
Ethnicity						
Native Hawaiian	357	100.0			357	83.2
< 25% Native Hawaiian	11	3.1			11	2.6
25%-49% Native Hawaiian	55	15.4			55	12.8
50%-74% Native Hawaiian	117	32.8			117	27.3
75%-100% Native Hawaiian	55	15.4			55	12.8
Declined to specify blood quantum	119	33.3			119	27.7
Non-Hawaiian			72	100.0	72	16.8
Age group, y						
18-34	124	35.1	21	30.4	145	33.8
35-49	114	32.3	25	36.2	139	32.4
50-64	79	22.4	19	27.5	98	22.8
65+	36	10.2	4	5.8	40	9.3
Household income, \$						
0-9,999	66	19.5	8	11.3	74	17.2
10,000-24,999	75	22.2	17	23.9	92	21.4
25,000-39,999	86	25.4	18	25.4	104	24.2
40,000-59,999	66	19.5	11	15.5	77	17.9
60,000+†	40	11.8	16	22.5	56	13.1
Declined to answer	24	6.7	2	2.8	26	6.1
Employment status						
Not employed	17	4.8	0	0	17	4.0
Employed‡	240	67.2	62	86.1	302	70.4
Homemaker	23	6.4	5	6.9	28	6.5
Student†	21	5.9	0	0	21	4.9
Retired	41	11.5	5	6.9	46	10.7
Education						
Some high school	30	8.5	4	5.6	34	7.9
High school or GED	108	30.4	14	19.7	122	28.4
Technical school	11	3.1	0	0	11	2.6
Some college or college degree	176	49.6	43	60.6	219	51.0
At least some graduate education	26	7.4	8	11.3	34	7.9
Religion						
Protestant‡	173	48.5	21	29.2	194	45.2
Catholic‡	83	23.2	29	40.3	112	26.1
Mormon	69	19.3	8	11.1	77	17.9
None†	15	4.2	8	11.1	23	5.4
Ever had surgery	174	48.7	37	51.4	211	49.2
Ever had cancer-related surgery	26	7.3	8	11.1	34	7.9
Participated in medical research†	64	17.9	5	6.9	69	16.1
Gave blood or tissue for research	43	12.0	6	8.3	49	11.4

*Percentages may not sum to 100 because participants could decline to answer specific questions.

†P < .05.

‡P < .01.

tion. Nearly half of our sample (49.2%) reported having had surgery, and 7.9% reported having had a cancer-related surgery. Only 16.1% had participated in medical research prior to this study, and 11.4% had given blood or tissue for a research study.

Comparison of Native Hawaiian and non-Hawaiian sociodemographics revealed significant differences in household income, employment status, and religion. Among Native Hawaiians, there were a greater proportion of respondents with a household income exceeding \$60,000 ($P < .05$), a smaller proportion of employed respondents ($P < .01$), a greater proportion of students ($P < .05$), a smaller proportion of Catholic respondents ($P < .01$), a greater proportion of Protestant respondents ($P < .01$), a smaller proportion of nonreligious respondents ($P < .05$), and a greater proportion of respondents who had participated in medical research ($P < .05$).

Table 2 presents the proportion of Native Hawaiian and non-Hawaiian respondents who would require informed consent for genetic research protocols using stored biological specimens that were personally identified, anonymous, and ethnically identified. Native Hawaiians were more likely than non-Hawaiians to require informed consent for the use of any type of stored specimen, and they were significantly more likely to require informed consent for specimens that contained ethnic identifiers ($\chi^2_{(1)} = 7.712, P < .01$). Both Native Hawaiian and non-Hawaiian participants were significantly more likely to think that consent should be required for the use of personally identified specimens (vs anonymous specimens; $P < .001$). Additionally, Native Hawaiian respondents were significantly more likely to require consent for ethnically identified specimens than for anonymous specimens ($P < .001$).

Table 3 shows preferences for dissemination of findings from genetic research protocols that use stored biological specimens. There were no statistical differences between preferences of Native Hawaiians and non-Hawaiians. Overall, 87.6% of respondents would personally want to know the research findings, and 79.0% would want research findings disclosed to their physicians.

TABLE 2. Frequency and Percentage of Respondents Who Would Require Informed Consent for Genetic Research*

Genetic Research	Native Hawaiians†		Non-Hawaiian‡	
	N	%	N	%
Identified	289	81.0	56	77.8
Anonymized	146	40.9	25	34.7
Ethnically Identified§	183	51.3	24	33.3

*Comparison of Native Hawaiian and non-Hawaiian participants accrued to 'Imi Hale's study addressing preferences for informed consent and dissemination of results from genetic research.⁹

†n = 357.

‡n = 72.

§ $\chi^2 = 7.712, P < .01$.

TABLE 3. Frequency and Percentage of Respondents Who Would Require Disclosure of Results From Genetic Research That Uses Stored Biological Specimens*

Disclosure	Native Hawaiian†		Non-Hawaiian‡		Overall§	
	N	%	N	%	N	%
Would want to know results	314	88.0	62	86.1	376	87.6
Would want physician to know results	280	78.4	59	81.9	339	79.0

*Comparison of Native Hawaiian, non-Hawaiian, and all participants accrued to 'Imi Hale's study addressing preferences for informed consent and dissemination of results from genetic research.⁹

†n = 357.

‡n = 72.

§N = 429.

Findings from logistic regression analysis (not shown in a table) revealed that respondents who were Protestant (odds ratio [OR], 5.11; 95% confidence interval [CI], 1.32-19.75) or Catholic (OR, 6.09; 95% CI, 1.51-24.50) were significantly more likely than nonreligious participants to think that informed consent should be required for the use of personally identified specimens in genetic research. For the use of anonymous specimens, respondents were significantly more likely to require informed consent if they were female (OR 1.78; 95% CI, 1.03-3.09), and they were significantly less likely to require informed consent if they were older (OR, 0.98; 95% CI, 0.95-0.99) or if they had a history of surgery (OR, 0.55; 95% CI, 0.32-0.94). For the use of ethnically identified specimens, respondents were significantly more likely to require informed consent if they were female (OR, 2.04; 95% CI, 1.17-3.57), if they were Native Hawaiian (OR, 2.91; 95% CI, 1.49-5.68), or if they had postsecondary education (OR, 4.99; 95% CI, 1.09-22.90).

DISCUSSION

Because our study relied on a nonrandom convenience sample, which included relatively few non-Hawaiians, our findings cannot generalize to the Native Hawaiian population or the general population. In the future, we recommend that similar studies use more rigorous sampling methods, which can be achieved by adding appropriate items to national random-sample surveys such as the Behavioral Risk Factor Surveillance Survey.¹⁰ In addition, although we were able to compare Native Hawaiian and non-Hawaiian respondents, it should be noted that the 2 groups differed on some sociodemographic characteristics including household income, employment status, religion, and participation in medical research. Of these, only religion was significantly associated with a preference for informed consent and therefore should be viewed as a potential confounding variable.

It is also possible that participant responses reflected a lack of awareness about issues related to research, genetic re-

search, and the use of biological specimens in research given that only 16.1% of our participants had experience with medical research, and less than half of these had experience with research that involved the use of a biological specimen. Although it may be prudent for future assessments to include persons with past research involvement, it should be noted that a national study by Wendler and Emanuel⁸ found no difference between the preferences of individuals who had previously participated in a research protocol requiring the use and storage of a biological specimen and those of other individuals who had not participated in research.

Despite these limitations, we present our study as a first step in assessing Native Hawaiian preferences for informed consent and dissemination of results from genetic research that uses stored biological specimens. Overall, we found that Native Hawaiians in our sample were more likely than non-Hawaiians to think that informed consent should be required for the use of stored specimens in research whether or not they contained identifiers but especially when they contained ethnic identifiers. Also, most Native Hawaiians and non-Hawaiians in our sample would want results from genetic research reported back to them and to their physicians.

Our findings also suggest that a number of factors may affect how participants think about genetic research and research that uses stored biological specimens. For example, Protestant and Catholic respondents were more likely than nonreligious respondents to think that informed consent should be required, perhaps reflecting the influence of religious values and beliefs. An age-related trend suggests a possible cohort effect in that younger adults may be more likely to require informed consent because they are more aware of research risks and benefits than are older adults. An increase in awareness may also explain the fact that individuals with more education were more likely to require informed consent. Gender differences could stem from the fact that men tend to underutilize the health care system and would be less likely than women to want to interact with medical researchers. Likewise, respondents who had prior surgery might be less likely to require consent because their prior experience has made them more trusting of the medical system. Finally, the fact that Native Hawaiians were more likely than non-Hawaiians to think that informed consent should be required, especially for ethnically identified specimens, suggests that Native Hawaiians may engender a different set of interests and concerns with respect to genetic research.

Indeed, several factors set Native Hawaiians apart from other ethnic groups beginning with the fact that these indigenous peoples of Hawai'i have a history of discrimination and abuse, resulting in a generalized distrust of research.^{4,11} Native Hawaiians also have a number of traditional beliefs that specifically forbid the desecration of tissue and body parts, especially of the deceased, on the basis that they contain *mana* or the very life force of the individual.¹² Finally, Native Hawaiians also view health as holistic and collectivistic, and they view disease as an imbalance in the physical world, in social relations, and in spiritual life that

can be remedied through native healing practices.^{4,13} As such, Native Hawaiians may feel unsettled by research that takes place without informed consent, research that involves biological specimens, and research that negates cultural beliefs about health and healing.

As a vulnerable minority group that has experienced economic, legal, and social disadvantage and discrimination, Native Hawaiians may also have concerns that are heightened in the arena of genetic research, most notably the fact that psychological and social harms (eg, stigmatization, discrimination in employment, social and political status, and eligibility for marriage and insurance) can affect not only the research participant but also the past, present, and future members of one's family, community, and population.^{3,4} Similar to other indigenous groups, Native Hawaiians who participate in research may also feel exploited when researchers and institutions profit greatly from the commercialization of genetic information, while benefits do not extend to the individuals, families, and communities whose genes are being studied.^{3,4,14}

As agencies like the National Institutes of Health continue to emphasize the importance of including minorities in all types of research,¹⁴ there will be an even stronger movement to bear out ethnic differences in disease both genetic and otherwise. Ideally, the aims of this type of research will be (1) to test and generate hypotheses that lead to greater understanding of ethnic differences in disease and (2) to ensure that research risks and benefits are equitably distributed in a given population.^{15,16} However, as Corbie-Smith, Miller, and Ransohoff¹⁶ pointed out, "focusing on possible differences by race has the potential to reify racial classifications rather than identify explanatory factors, and may justify inequities rather than lead to reduced disparities," and this may be especially true for genetic research.

Given the potential for both individual and group harm as a result of genetic research that uses stored biological specimens, we advocate for minorities to be viewed not only as potential research subjects but as partners in all levels of the research process according to the tenets of the community-based participatory research model.¹¹ If "at-risk" groups are allowed to exert some control over the research process (eg, through voicing their preferences for informed consent and disclosure of research results), it is more likely that research protections will be both necessary and sufficient for the individuals and groups that are involved, thereby minimizing potential risks.

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