Appendix A
Public Knowledge, Belief, and Feelings About Research Use of Human Biological Materials

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BACKGROUND

The National Bioethics Advisory Commission (NBAC) saw the value in ascertaining the opinions of members of the American public meaning those who are not medical researchers or ethical experts regarding the used of stored human biological materials. Public opinion provides additional information for consideration. NBAC contracted with the Center for Health Policy Studies (CHPS) to study these issues and to gather a selection of public opinion regarding the use of stored samples.

STUDY PURPOSE

The purpose of this study was to explore public knowledge, beliefs, and feelings about human biological materials issues. These were elicited around five distinct areas of inquiry:

- consent and ownership
- privacy and confidentiality
- stigmatization of ethnic groups
- third party concerns
- sponsorship of research
- safeguards

CHPS held public discussion forums across the country to get a sense of what the American public believes and feels about uses of stored samples, the ethical obligations of those who may learn significant health risk information from such samples, and privacy protections. Forum locations included Richmond, Virginia; Honolulu, Hawaii; Mililani, Hawaii; San Francisco, California; Cleveland, Ohio; Boston, Massachusetts; and Miami, Florida.

Knowledge About Tissue Storage

At the beginning of each forum, participants were asked a number of questions to assess their knowledge of sample storage prior to the discussion of specific issues. Groups were asked to identify what items may be classified as human biological materials and ways that such materials can be collected. Participant's knowledge regarding the use of tissue for research was also assessed.

Across groups, participants generally understood what constitutes human biological material and what it can reveal about people. Most participants had never considered what happens to samples once they have been used for their initial purposes. Many believed that samples were destroyed or discarded. One exception was a participant in the Honolulu forum who knew that tissue could be stored for later re-testing or for comparison purposes. Many participants stated that they had had tissue removed during a medical or surgical procedure, although not all of them recalled the issues covered in the consent forms or even if they had signed consent forms. Most were not sure whether the consent forms they had signed discussed the disposition of the tissue sample.

Beliefs and Attitudes About Storage of Human Biological Materials

The following sections present findings from forums regarding the publics' beliefs and attitudes. Discussed are participants' responses to hypothetical scenarios regarding issues pertaining to ownership and consent; privacy and confidentiality; stigmatization of ethnic groups; third party concerns; sponsorship of research; and safeguards for research.

Ownership and Consent

Regarding ownership, many participants felt that if consent was provided for a procedure during which specimens were removed, then the hospital or provider owns the specimen. A few felt that the individuals from whom materials are taken should own the sample. Participants in one of the Hawaii forums made the distinction between the hospital or provider owning the sample and patients owning information that may be revealed by the sample.

Participants were also asked whether specific consent should be obtained from patients to use specimens for research, and if they would want to consent to each potential study of their tissue. There were varying opinions across groups regarding this issue. Some felt that there was no need to specifically consent to research on their stored sample, especially if samples are anonymous. Other participants, particularly in Cleveland and Miami, wanted to provide consent for each potential study of their tissue. Many felt that a general, one-time consent (i.e., blanket consent) for research was enough.

Privacy and Confidentiality

Participants were asked to share their feelings about their privacy rights and the importance of confidentiality. Issues concerning insurance companies' access to research results, linkages between names and research, and potential threats to confidentiality were discussed. Overwhelmingly, forum participants felt strongly that insurance companies should not have access to results of genetic research on stored samples.

Across groups, participant views varied when considering how to balance the advantages of research into genetic diseases with possible abuses to privacy. In general, most felt positively about medical research. Participants in the two Hawaii forums and in San Francisco were vocal about the importance of medical research, and they were not concerned about potential abuses to their privacy. Participants in Cleveland and Miami were more concerned about the protection of their privacy rights. Many participants across forum sites stated that they wanted to be notified if researchers later discovered medically useful information about them from stored samples, although some participants in Cleveland disagreed and felt that their privacy was more important. Some participants in Boston felt that it was important to define what comprises "medically useful information," since they did not consider findings that indicate propensity for disease to meet their criteria for notification. San Francisco participants felt strongly that their physicians, not researchers, should relay research results.

Most participants agreed that use of anonymous samples for research was acceptable and necessary for the public good. Moreover, most participants across groups were not concerned about the linkage of certain facts (e.g., age, sex, ethnic group) with their stored samples, although participants in Miami wanted to ensure that their privacy was maintained. There was diversity of opinion regarding linking identifying information with stored samples. Most participants in Hawaii, San Francisco, and Miami felt that linked research was acceptable and appropriate. Many participants in Cleveland and some in Boston did not want any links between their stored samples and their identities.

Across localities, participants balked when asked to consider what would happen if confidentiality of research findings were not maintained. Instead, they believed that privacy and confidentiality could not be ensured due to the sophistication of computers and the commercial health care environment.

Stigmatization of Ethnic Groups

Forum participants were asked how they felt about researchers studying specific groups of people, such as ethnic or racial groups. Groups were specifically probed to consider whether such research could potentially stigmatize certain groups of people. Generally, participants across forums did not express concern that research could stigmatize specific groups. Participants in most groups, however, mentioned that there could be negative impacts from this research, such as issues with insurance coverage for the groups being studied and the potential to disseminate research findings prematurely that might later be disproved. Participants in all groups mentioned that the groups being studied generally tended to benefit from such research and gave the examples of research on Tay Sachs disease and sickle cell disease.

Third Party Concerns

Forum participants responded to a number of questions regarding genetic research in which one person's stored sample could reveal information about family members. Across forums, participants had mixed feelings about how and under what circumstances family members should be informed of such research. Many participants stated that they would want to be informed if genetic research revealed information about them. Some recognized, however, that

many family members might not want to know, and there were issues regarding who should inform family member of such research results (e.g., physicians, researchers, or the individuals from whom the tissue was taken). When asked if family members should be provided the opportunity to consent to a study of their relative's tissue, most felt that this would be inappropriate and difficult to achieve. Across groups, most participants did not feel that there were negative consequences from studying diseases that tend to run in families.

Participants were also asked who should make decisions about sample storage for those who are unable to make such decisions. Categorically, participants felt that legal guardians or medical surrogates should make these decisions, and some were vocal that individuals' preferences should be considered whenever possible (e.g., for children).

Sponsorship of Research

Participants discussed how they felt about researchers accessing their stored samples and if it mattered who was sponsoring the research, i.e., a for-profit company, a university, or the federal government. Most participants felt that researchers should be able to gain access to stored samples, although a few believed that there were differences between research conducted by different entities. Some participants in Cleveland, Boston, and Miami felt that the profit motives of biotechnology and pharmaceutical companies differentiated their research from academic research. Most participants in Richmond, Mililani, and San Francisco felt that there were no differences between the various sponsors of research.

Across groups, it did not matter to many participants if firms could profit from research on stored samples. A few participants in the Boston and Miami forums, however, expressed some discomfort about the profit motives of these firms. A few participants in Honolulu and Miami felt that they would want to share in profits that may result from research on their stored sample, while overall, most participants felt it was unimportant or impractical.

Safeguards

Participants were asked about issues related to safeguards for research and medical information. Across localities, people felt that researchers should have to receive approval from a committee or other entity that oversees the ethics of research, prior to conducting research on stored tissue. When asked who should review and oversee research, participants identified individuals that typically comprise institutional review boards. In addition, some felt those representatives of the groups being studied and ethical people (regardless of profession) should be included. When asked who they trusted to protect medical information that is available about them, no group was categorically identified that could be trusted.