

1 **Appendix A**
2 **Public Knowledge, Belief, and Feelings**
3 **About Research Use of Human Biological Materials**

4
5 **BACKGROUND**

6
7 The National Bioethics Advisory Commission (NBAC) saw the value in ascertaining the opinions
8 of members of the American publicXmeaning those who are not medical researchers or ethical
9 expertsXregarding the used of stored human biological materials. Public opinion provides
10 additional information for consideration. NBAC contracted with the Center for Health Policy
11 Studies (CHPS) to study these issues and to gather a selection of public opinion regarding the
12 use of stored samples.

13
14 **STUDY PURPOSE**

15
16 The purpose of this study was to explore public knowledge, beliefs, and feelings about
17 human biological materials issues. These were elicited around five distinct areas of inquiry:

- 18
19 • consent and ownership
20 • privacy and confidentiality
21 • stigmatization of ethnic groups
22 • third party concerns
23 • sponsorship of research
24 • safeguards

25
26 CHPS held public discussion forums across the country to get a sense of what the
27 American public believes and feels about uses of stored samples, the ethical obligations of those
28 who may learn significant health risk information from such samples, and privacy protections.
29 Forum locations included Richmond, Virginia; Honolulu, Hawaii; Mililani, Hawaii; San Francisco,
30 California; Cleveland, Ohio; Boston, Massachusetts; and Miami, Florida.

31

September 4, 1998: This is a draft report developed for the National Bioethics Advisory Commission. It does not represent conclusions and should not be cited or referenced.

1 **FINDINGS**

2

3 **Knowledge About Tissue Storage**

4

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

10

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

20

21 **Beliefs and Attitudes About Storage of Human Biological Materials**

22

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

27

28 **Ownership and Consent**

29

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

1
2 Participants were also asked whether specific consent should be obtained from patients to
3 use specimens for research, and if they would want to consent to each potential study of their
4 tissue. There were varying opinions across groups regarding this issue. Some felt that there was
5 no need to specifically consent to research on their stored sample, especially if samples are
6 anonymous. Other participants, particularly in Cleveland and Miami, wanted to provide consent
7 for each potential study of their tissue. Many felt that a general, one-time consent (i.e., blanket
8 consent) for research was enough.

9 10 **Privacy and Confidentiality**

11
12 Participants were asked to share their feelings about their privacy rights and the
13 importance of confidentiality. Issues concerning insurance companies' access to research results,
14 linkages between names and research, and potential threats to confidentiality were discussed.
15 Overwhelmingly, forum participants felt strongly that insurance companies should not have access
16 to results of genetic research on stored samples.

17
18 Across groups, participant views varied when considering how to balance the advantages
19 of research into genetic diseases with possible abuses to privacy. In general, most felt positively
20 about medical research. Participants in the two Hawaii forums and in San Francisco were vocal
21 about the importance of medical research, and they were not concerned about potential abuses to
22 their privacy. Participants in Cleveland and Miami were more concerned about the protection of
23 their privacy rights. Many participants across forum sites stated that they wanted to be notified if
24 researchers later discovered medically useful information about them from stored samples,
25 although some participants in Cleveland disagreed and felt that their privacy was more important.
26 Some participants in Boston felt that it was important to define what comprises "medically useful
27 information," since they did not consider findings that indicate propensity for disease to meet their
28 criteria for notification. San Francisco participants felt strongly that their physicians, not
29 researchers, should relay research results.

30
31 Most participants agreed that use of anonymous samples for research was acceptable and
32 necessary for the public good. Moreover, most participants across groups were not concerned
33 about the linkage of certain facts (e.g., age, sex, ethnic group) with their stored samples, although
34 participants in Miami wanted to ensure that their privacy was maintained. There was diversity of
35 opinion regarding linking identifying information with stored samples. Most participants in
36 Hawaii, San Francisco, and Miami felt that linked research was acceptable and appropriate. Many

September 4, 1998: This is a draft report developed for the National Bioethics Advisory Commission. It does not represent conclusions and should not be cited or referenced.

1 participants in Cleveland and some in Boston did not want any links between their stored samples
2 and their identities.

3
4 Across localities, participants balked when asked to consider what would happen if
5 confidentiality of research findings were not maintained. Instead, they believed that privacy and
6 confidentiality could not be ensured due to the sophistication of computers and the commercial
7 health care environment.

8 9 **Stigmatization of Ethnic Groups**

10
11 Forum participants were asked how they felt about researchers studying specific groups of
12 people, such as ethnic or racial groups. Groups were specifically probed to consider whether
13 such research could potentially stigmatize certain groups of people. Generally, participants across
14 forums did not express concern that research could stigmatize specific groups. Participants in
15 most groups, however, mentioned that there could be negative impacts from this research, such as
16 issues with insurance coverage for the groups being studied and the potential to disseminate
17 research findings prematurely that might later be disproved. Participants in all groups mentioned
18 that the groups being studied generally tended to benefit from such research and gave the
19 examples of research on Tay Sachs disease and sickle cell disease.

20 21 **Third Party Concerns**

22
23 Forum participants responded to a number of questions regarding genetic research in
24 which one person's stored sample could reveal information about family members. Across
25 forums, participants had mixed feelings about how and under what circumstances family members
26 should be informed of such research. Many participants stated that they would want to be
27 informed if genetic research revealed information about them. Some recognized, however, that
28 many family members might not want to know, and there were issues regarding who should
29 inform family member of such research results (e.g., physicians, researchers, or the individuals
30 from whom the tissue was taken). When asked if family members should be provided the
31 opportunity to consent to a study of their relative's tissue, most felt that this would be
32 inappropriate and difficult to achieve. Across groups, most participants did not feel that there
33 were negative consequences from studying diseases that tend to run in families.

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

6 **Sponsorship of Research**

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

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

23 **Safeguards**

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