

1 **Chapter 4** 2 **Ethical Perspectives on the Research Use** 3 **of Human Biological Materials**

4
5
6 For centuries, the scientific study of the human body has produced important medical
7 information. Current uses of human biological materials for diagnostic, therapeutic,
8 research, and educational purposes continue this pattern, but they also raise ethical issues
9 for research subjects, their families, investigators, investigators, institutional review
10 boards, and the society (Merz, 1997; Merz, Leonard, and Miller, 1999). This chapter
11 examines several ethical issues, many of which have already surfaced in preceding
12 chapters, and it provides the background for the recommendations that follow in Chapter
13 5.

14
15 As observed in Chapter 2, some human biological materials have been stored for decades,
16 millions more will be gathered and stored in the next year, tens of millions more in the
17 next decade. The individuals who are the sources of these samples are identifiable in
18 some cases, but not in others. Some specimens were gathered during clinical procedures,
19 such as surgery, for which informed consent was obtained, but some were not. Even
20 when there was informed consent for the procedure that produced the specimen, the
21 sources may not have consented to possible future uses of the material. In many--perhaps
22 most -- cases, individuals had no idea that their specimen was being stored or any
23 knowledge that it might be used for various research purposes by a variety of
24 investigators.

25
26 Obtaining information by taking a medical history or by interpreting the tracings on an
27 electrocardiogram may not have the same significance for many individuals and their
28 family members as biopsying a piece of tissue or drawing blood. The reason is that many
29 of the interests at stake for the sources of the biological materials center on the additional
30 information that those materials can yield, for instance, in predicting an individual's
31 future health course. Some types of medical research, particularly genetic research,
32 reveal information not only about the individual sources of the biological materials but

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1 also about members of their families or groups with which they share certain
2 characteristics. In addition, any cell from any part of the body can be subjected to genetic
3 analysis because the nucleus of every cell of the body (with the exception of red blood
4 cells and reproductive cells) contains the complete genetic code of the person from whom
5 the sample was taken. For all these reasons, and because of deep concerns about possible
6 uses of genetic information, there is widespread interest in ethical constraints on practices
7 of gathering and storing human biological samples that may be used for research.

8

9 This chapter draws on the three principles--beneficence, respect for persons, and justice--
10 that, since their formulation by the National Commission for the Protection of Human
11 Subjects of Biomedical and Behavioral Research in its influential Belmont Report, have
12 provided a broad ethical framework for assessing and directing research involving human
13 subjects. (National Commission, 1979). That report was intended "to provide an
14 analytical framework [to] guide the resolution of ethical problems arising from research
15 involving human subjects." (National Commission, 1979) This chapter also draws on the
16 ethical guidance provided by federal regulations for protecting human research subjects,
17 as well as laws, policies and professional codes that bear on this subject. Particularly
18 important are rules pertaining to privacy and confidentiality, which are now the subject of
19 considerable societal debate in relation to computerized medical records and genetic
20 research. In addition, this chapter attends to perspectives offered by bioethicists and
21 others on the research use of human biological materials (Buchanan 1998; Campbell,
22 1998) Several bioethicists have argued, for instance, that excessively individualistic
23 interpretations of the ethical principles and rules governing research involving human
24 subjects fail to attend to relevant groups and communities. NBAC does not assume that
25 all these sources of ethical guidance are equally authoritative or insightful.

26

27 While drawing on all of them, NBAC provides its own analysis of the major ethical
28 issues and argues for ways to address the relevant moral concerns. Part of the analysis
29 will consider the extent to which research using stored tissue samples falls under the
30 moral principles and rules that ordinarily govern research with human subjects and the
31 extent to which it is distinctive.

1 In making ethical judgments about the research use of human biological materials, it is
2 not always necessary to pit the interests of future beneficiaries of current research against
3 the interests of those who have provided the human biological material in not being
4 wronged or harmed. First, scientists share the moral (and often legal) obligation to design
5 their experiments to minimize possible harms and wrongs to subjects. Second,
6 individuals often eagerly participate in research studies because of their feelings of
7 altruism or general social benevolence. Third, some patients may participate in research
8 because they hope to benefit, now or in the future, from new scientific and medical
9 developments. Thus, virtually all parties to the discussion acknowledge both the value of
10 biomedical research and the need to minimize harms and wrongs. Indeed, the challenge
11 is not to trade off potential health benefits from research against protections of sources
12 and others, but rather to find ways to maximize the opportunities for developing new
13 knowledge and new treatments while, at the same time, ensuring appropriate protections
14 from harms and wrongs. Only then will the public have trust in researchers and
15 confidence in research.

17 **Promoting Benefits and Minimizing Harms and Wrongs**

19 According to the National Commission, "[b]eneficence ...requires that we protect against
20 risk of harm to subjects and also that we be concerned about the loss of the substantial
21 benefits that might be gained from research." (National Commission, 1979.) The
22 principle of beneficence thus encompasses not only research efforts to produce
23 generalizable knowledge that can benefit society, but also efforts to avoid harming
24 persons, to minimize possible harms, and to assess possible harms in relation to possible
25 benefits. Researchers, IRBs, and others have an obligation to minimize harms and the
26 risks of harm to research subjects.

28 All harms may be viewed as set-backs to interests (Feinberg 1984), but then it is
29 necessary to identify and, where possible, assign weights to various interests of both
30 individuals and groups. Rather than simply trying to set those interests out in abstraction
31 from a particular context, this chapter considers them in relation to the principles,

1 regulations, and guidelines that already identify many of the relevant harms and assign
2 them some weights relative to each other, sometimes by setting certain presumptions and
3 indicating the conditions under which those presumptions can be rebutted.

4
5 In addition to harms, at least narrowly construed, there are wrongs to individuals and
6 groups, for example, in the violation of rights such as a right to privacy. Not every
7 wrong, such as an unjustified breach of privacy, is itself a harm or even causes a harm.
8 For instance, if someone enters our house and rummages through our personal
9 possessions, but takes nothing and leaves everything exactly as it was before so that we
10 don't know that anything occurred, it is appropriate to say that we have been wronged,
11 because our right to privacy was violated, even though no harm occurred. People may be
12 harmed without being wronged and wronged without being harmed. In short, an ethical
13 framework needs the concept of wrongs as well as the concept of harms.

14
15 NBAC's analysis starts from the assumption that the potential harms to individuals and
16 groups through research on human biological materials will usually be non-physical.
17 They arise not from "touching" a person (as in most clinical research interventions), but
18 from the acquisition, use, or dissemination of information obtained from the sample
19 itself. Obviously, the easier it is to connect sources of biological materials with those
20 materials and the more widely available the information linking sources and samples, the
21 greater the concern about risks to the individuals involved. Hence, different ethical
22 judgments may be appropriate for anonymous, unlinked, coded, and identified samples.
23 In addition, rules of privacy and confidentiality, which are distinguished but closely
24 connected, often protect individuals from unwanted and potentially harmful disclosures
25 of information about them. Such rules reflect not only efforts to respect persons (see the
26 discussion below), by authorizing them to decide how much access to this information
27 they will grant to others, but also to protect them from potential harms from the
28 unauthorized disclosure of that information.

29
30 **Potential Harms from Breaches of Privacy and Confidentiality**

31

1 *Privacy and Confidentiality.* Privacy refers to a state or condition of limited access to an
2 individual, including access to information about that individual. And rules of privacy or
3 rights to privacy enable individuals to maintain their privacy. Some definitions of
4 "privacy" conflate privacy, which refers a state or condition, with a right to privacy,
5 which refers to the individual's right to control access to himself or herself. However,
6 it is useful to distinguish privacy from a right to privacy because individuals can have
7 privacy without having any control over others' access -- others may simply ignore them,
8 and they can have a right to privacy that is not sufficient to guarantee their privacy.
9 (Ref.)

10

11 Privacy is a multilayered concept. For example, Anita Allen identifies four dimensions
12 of "genetic privacy" -- informational, decisional, physical and proprietary (Allen 1997).
13 She observes that "genetic privacy" refers principally to informational privacy (Westin,
14 1994), but that each of the other three dimensions may also be implicated in genetics.
15 Physical privacy focuses on persons and personal spaces; decisional privacy on an
16 individual's decisionmaking, and proprietary privacy focuses on appropriation and
17 ownership. All four dimensions may be expressed in concerns about privacy in the
18 context of human biological materials.

19

20 People have an interest in not being subjected to unnecessary exposure of the body to the
21 view of others and in not having embarrassing or intimate facts about themselves
22 disclosed, even if such exposure or disclosure does not threaten other interests they may
23 have or produce other harms. Concerns about privacy are often closely related to
24 concerns about dignity, since in most, if not all, cultures some modes of exposing the
25 body, in some contexts, are considered undignified and demeaning, and some intimate
26 information is considered embarrassing and even shameful.

27

28 For the most part, once the biological material is removed from the body, it is the interest
29 in confidentiality, rather than the interest in privacy, that is at issue. Confidentiality
30 emerges when one person makes available information to another person, whether

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1 through verbal communication, a physical examination, an analysis of biological tissue,
2 or some other means, and the person who gains access to that information pledges not to
3 disclose it to others without the confider's authorization. When people grant others
4 access to themselves in health care and research – for example, through the providing
5 biological materials for examination—they necessarily surrender some of their privacy,
6 but they often want to restrict further access to the information that emerges. Rules of
7 confidentiality, and rights to confidentiality, expressed in professional codes, laws, and
8 regulations, authorize individuals to maintain confidentiality within certain limits.

9
10 In this report confidentiality mainly concerns access to and use of information physically
11 contained in a database, such as a medical record. People often want information about
12 them kept in confidence, particularly when there has been a prior agreement or
13 expectation that further access to their biological materials and to the information these
14 materials contain will be appropriately limited. Although such confidentiality protections
15 are provided for in federal regulations (45 CFR 46.116(a)(5)), nothing in regulation will
16 provide total protection against the inadvertent disclosure of such information. In
17 addition, rules of confidentiality are rarely considered absolute and various exceptions are
18 recognized. What counts as an justifiable limitation on or exception to confidentiality
19 will depend upon a complex weighing of conflicting legitimate interests.

20
21 Many of the risks to sources of biological materials--and to others--flow from access to
22 those materials and the information they provide, often from breaches of confidentiality,
23 sometimes from breaches of privacy.

24
25 *Discrimination in Health Insurance and Employment.* In remarks made during an event
26 in the East Room of the White House on July 14, 1997, President Clinton expressed the
27 hope that American citizens would not be forced to "choose between saving their health
28 insurance and taking tests that would save their lives" (See Box 1). The President was
29 referring to the challenge facing people who are concerned that genetic information might
30 be used to unfairly discriminate against them. Moreover, being listed in a tumor registry
31 or replying truthfully to questions about one's family medical history may be just as risky

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1 as having a positive test for a genetic disorder reported in one's medical records. Given
2 current social and institutional arrangements, persons known to have health problems or
3 susceptibility to diseases may be at risk of discrimination in obtaining and keeping health
4 insurance and employment.

5

6 Although some evidence is available (Lapham, 1996), the actual extent of insurance and
7 employment discrimination on genetic grounds remains a matter of speculation because
8 most of the evidence comes from surveys in which individuals self report discrimination,
9 with little or no independent verification of the accuracy of their perceptions (Billings,
10 1992). Moreover, the risk exists only for insurance policies whose issuance is conditional
11 on individual medical underwriting, and most Americans who have private health
12 insurance obtain it through employment-based, large-group policies in which there is no
13 individual medical underwriting. Nevertheless, some forms of individual underwriting
14 may affect tens of millions Americans (Stone, in Murray, 1996).

15

16 Wertz (1997) has reported data from geneticists, primary care physicians, and a sample of
17 patients following genetic counseling on a number of topics, including genetic
18 discrimination. These sources revealed few instances of employment or insurance refusal.
19 Still the geneticists reported that about 550 individuals were refused employment, fired,
20 or denied life insurance on genetics grounds. In a Harris Poll, commissioned by Wertz
21 and involving 1000 adults, 3 percent of the general public reported being refused
22 employment or fired, 3 percent reported being denied health insurance, and 5 percent
23 reported being denied life insurance "because of an inherited disease or condition."
24 These data are worth considering, and should be followed up. Insurance or employment
25 discrimination could, of course, have devastating consequences for individuals and for
26 their families.

27

28 The policies needed to reduce the risks of insurance or employment discrimination vary
29 with the magnitude (both probability and severity) of those risks, and hence with the
30 institutional arrangements that either magnify or diminish those risks. For example, if
31 blood were collected from identifiable individuals for use in a study of the basic

1 biological mechanisms of platelet formation, one could argue that the risk of disclosure of
2 that information poses little, if any, risk of discrimination to the individual who donates
3 the blood. If, however, the very same specimens were then later used to determine
4 whether trace amounts of alcohol could be found in the blood, the potential for
5 discrimination, and therefore concern, increases. And if that blood were collected in the
6 context of the workplace, concerns about the potential for discrimination would become
7 even more pronounced.

8

9 The risk of insurance discrimination is not an inevitable effect of the existence of
10 information about illness or susceptibility; instead it is a byproduct of the current
11 structure of the U.S. insurance market, in which most medical insurance is employment-
12 based and in which some private insurers compete in part by attempting to avoid fully
13 insuring sick (and therefore costly) individuals. If this particular set of institutional
14 arrangements were abolished or modified in certain ways, the risk of discrimination in
15 health insurance could decrease substantially. At the same time, the case for restricting
16 access to biological sample information in order to reduce the risk of insurance
17 discrimination would also decrease. It is also important to emphasize, however, that
18 discrimination in life insurance and disability insurance, as compared to health
19 insurance, could also occur in other countries, which depend on private insurance in these
20 areas (Knoppers, 1997). For example, as a recent discussion in the United Kingdom
21 reveals, there are important reasons for the insurance industry to carefully assess the
22 implications of distinguishing between "genetic" and "non-genetic" information
23 (Thomson, 1998).

24

25 It follows that where powerful institutions pose significant threats of discrimination on
26 the basis of genetic or other medical information, greater restrictions on access to
27 biological and medical information will be needed than in a society in which these threats
28 are absent. If federal and state laws prohibiting insurance and employment
29 discrimination on the basis of genetic and other medical information are passed and
30 effectively implemented, the balance between interests that weigh in favor of more

1 restricted access to and greater source control over biological samples, on the one hand,
2 and those that weigh in favor of freer access and more permissive research uses of those
3 samples, on the other hand, would shift accordingly. Therefore, any policies developed
4 now may need to be revised in the future.

5
6 *Stigmatization.* When disclosure of medical information occurs, an individual may suffer
7 the harm of stigmatization, even if he or she is not denied insurance or employment.
8 Stigmatization is closely related to discrimination. Like discrimination, stigmatization is
9 a form of exclusion by labeling, which often involves at least an intimation of
10 unwholesomeness, taint, or blame.

11
12 Stigmatization is usually imposed on individuals from without, by the negative
13 perceptions and judgments of others. However, individuals often also internalize those
14 negative external attitudes. Although there is an unfortunate tendency to focus only on
15 the stigmatization that results from being identified as having a genetic disorder, other
16 types of illness can be equally or even more stigmatizing (e.g., sexually transmitted
17 diseases, disfiguring diseases, and, in some cultures, cancer).

18
19 The reality and burden of stigmatization vary among individuals and depend on cultural
20 attitudes toward disease. For example, some might find it stigmatizing to learn, as the
21 result of participating in a research study, that they possess a genetic marker that
22 predisposes them to psoriasis, a condition that can be disfiguring. Others might not
23 consider this to be stigmatizing. Some consider it to be stigmatizing to be a Tay-Sachs
24 carrier because it has the potential to put the health of future children at risk; others who
25 have been found to be such carriers do not view the condition as stigmatizing (American
26 Jewish Congress, 1998). Stigmatization is not limited to associations between persons or
27 groups and certain diseases; stigma also may occur when studies perpetuate certain
28 stereotypes within ethnic or social groups.

29
30 Stigmatization is difficult to define and even harder to measure. When, in the future,
31 science can provide more information about the nature (and universal prevalence) of

1 genetic susceptibility to disease, and shares this information with the public, the risk of
2 stigmatization on genetic grounds may diminish. But more than this will be needed.
3 Given the difficulty with identifying and quantifying stigma, researchers and IRBs will
4 have to find ways to assess this issue in evaluating protocols that use human biological
5 materials.

6
7 *Familial Conflict and Other Psychosocial Harms.* In some instances, biological
8 information, like other medical information, may be a source of intra-familial conflict.
9 For example, genetic analysis of blood may reveal that the husband is not the father of
10 the child. Or if a daughter tests positive for Huntington's disease, she reveals the genetic
11 status of her parents, who might not want to know this devastating information. In some
12 cultures, a family learning that the prospective spouse of one of its members has a genetic
13 disorder or a certain medical condition may attempt to prevent the marriage from taking
14 place. Even if the beliefs back of such actions reflect mistaken views about genetics or
15 indefensible assumptions about responsibility for disease, the conflicts they can generate
16 and the resulting harms are quite real.

17
18 In addition, finding out that a member is, for example, a carrier for a genetic condition,
19 predisposed to heart disease, or infected with the HIV virus, can force families into
20 difficult situations, emotionally, physically, and economically. The knowledge that an
21 individual is at elevated risk for disease or may have unwittingly passed on a deleterious
22 genetic trait to his or her offspring is sensitive information that should be provided only
23 with the full knowledge and consent of the individual from whom the sample came.

24
25 *Group-Related Harms.* Closely related to discrimination and stigmatization is another
26 potential harm that individuals may suffer because of perceived links between medical
27 information about them contained in a biological sample and what may be called their
28 ascriptive (or group-based) identity. The harm of negative racial stereotyping, for
29 example, is a harm to individuals, but it befalls individuals because of their ascriptive
30 group identity. The term "ascriptive" here indicates that the identity in question is
31 assigned by others, independent of the choice of the individual thus identified.

1 Individuals who are vulnerable to ascriptive-identity harms have a special interest in
2 avoiding situations in which information obtained from their biological samples
3 contributes to the reinforcement of harmful stereotypes. Thus, it is arbitrary to limit
4 consideration of potential harms to those affecting the individual research subject,
5 especially given the power of new biomedical research technologies.

6

7 The harms that individual research subjects may suffer are harms that other members of
8 their ascriptive group who have not contributed samples may also suffer as a
9 consequence of the research. Research which is designed to study a group, or which
10 retrospectively implicates a group, may, for example, place the group at risk of being
11 perceived as unusually susceptible to disease. This, in turn, could result in members of
12 the group facing, among other things, stigmatization and discrimination in insurance and
13 employment whether or not they contributed samples to the study. What is at issue for
14 both the individual research subject and the group is that the research might expose
15 information about them -- namely, the higher probability of the occurrence of certain
16 diseases -- which places them at risk of psychosocial and other harms. An individual
17 whose identifiable sample reveals her or him to be especially susceptible to a disease may
18 be at greater risk of harm than those individuals about whom there does not exist such
19 specific information.

20

21 This fact sometimes justifies the special protections afforded the individual research
22 subject. However, there may be circumstances in which the individual research subject
23 faces less risk of harm than other members of a group to which he or she belongs. For
24 example, a socially and economically well situated research subject will likely be at less
25 risk of suffering the effects of insurance and employment discrimination than less
26 fortunate members of the group. Moreover, the stigma associated with a disease may be
27 far more injurious to a group than to a particular individual, especially where the group is
28 one that is already socially and politically marginalized. As research on human genetic
29 variation increases, additional ethical issues may arise regarding research on identified
30 groups, a concern that is now the subject of research (Foster, Bernsten, and Carter, 1998)
31 and a new priority for the federally funded human genome project (Collins, 1998).

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1 These examples of possible harms from the disclosure of information about sources of
2 biological materials and their families and other groups with which they are associated
3 obviously raise important ethical concerns about protecting both privacy and
4 confidentiality. Minimizing those harms, as required by the principle of beneficence,
5 dictates not only strengthening societal rules protecting privacy and confidentiality, but
6 also giving priority to procedures, such as using anonymous and unlinked samples where
7 possible, in order to minimize the risks to the sources and to others.

8

9 **Respecting Persons Who Are Sources of Biological Materials**

10

11 *Treating Persons as Moral Agents.* Each person has an interest in being treated as a
12 moral agent, that is, as an individual capable of exercising choices, with his or her own
13 values, preferences, commitments, and conceptions of the good. Part of the moral
14 justification for the requirement of informed consent in research and treatment is to
15 ensure that patients and research subjects are treated respectfully as agents, not as passive
16 objects to be used merely for the ends of others. More broadly, however, respecting
17 persons is essential to a relationship of trust between them and researchers who want to
18 use their biological materials. Still more broadly, the respect owed to individuals in using
19 information about them raises concerns about the dignity with which we are treated – a
20 concern recognized in the Universal Declaration on the Human Genome and Human
21 Rights, recently adopted by the United Nations General Assembly (United Nations,
22 1998).

23

24 A case can be made that current practices concerning human biological materials
25 sometimes fail to treat persons with due respect because researchers may unintentionally
26 mislead persons as to why materials are being gathered and to what uses they will be put.
27 It is true that the person who draws the blood may not know that it will be stored
28 indefinitely and may be used in any number of ways in the future and thus may have no
29 intention to mislead. Nevertheless, the institutionalized practice of storing biological
30 specimens for future uses is one for which those who control the practice are responsible,

1 and this practice, as we have seen, apparently does not always adequately inform
2 individuals about what may happen to the material.

3

4 *Informed Consent.* A fundamental ethical question raised by the research use of human
5 biological materials is what kind of consent, if any, is required from whom for what.
6 Informed consent is recognized to be both a legal and moral requirement for medical
7 interventions generally and for all experiments with human subjects that involve more
8 than minimal risks. In addition to review of research with human subjects by Institutional
9 Review Boards, informed consent has been a primary, albeit imperfect, means for
10 protecting the interests, welfare, and rights of individuals who are subjects of research.

11

12 As this chapter has indicated, risks are taken to include not only potential physical harms
13 from bodily invasions, but also psychosocial harms, especially stigmatization, and other
14 assaults on an individual's sense of self-worth. It is important to note that these harms are
15 not restricted to the minimal harms that might result from such techniques as drawing
16 blood or swabbing cells from the inside of the cheek. The point, rather, is that when
17 people allow others access to their bodies for these purposes, they become vulnerable to
18 other unwanted and more dangerous harms. For this reason, it is somewhat misleading to
19 say that the only harm from which a person is protected by informed consent for a simple
20 procedure such as drawing blood is the extremely remote possibility of harm from the
21 needle stick itself (beyond the unpleasant but momentary sensation of the prick itself).

22

23 Five elements of informed consent can be distinguished: 1) disclosure (of relevant risks
24 and benefits of the procedure); 2) competence (on the part of the patient or subject) to
25 make a decision whether to accept the treatment or participate in the research); 3)
26 comprehension (of the relevant risks and benefits); 4) choice (an expressed decision to
27 accept the treatment or participate in the experimentation); and 5) voluntariness (of the
28 choice to accept treatment or to participate in research). (Faden and Beauchamp, 1986).
29 Clearly, informed consent plays a role in any ethically sound system for collecting and
30 using biological samples at least to this extent: the requirement of informed consent must
31 be met for medical treatments generally and for most types of research. The question is

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1 whether an ethically sound system for collecting, storing, and using biological samples
2 will require additional or amplified applications of the requirement of informed consent
3 in order to express what the principle of respect for persons entails in this context and to
4 reduce the risks of the various wrongs and harms discussed in this chapter.

5

6 It is one thing to argue that the prevention of nonconsensual bodily invasion and
7 disrespectful treatment justifies restrictions on research and quite another to argue that the
8 mere possibility of various wrongs and harms, some of which may not be so serious and
9 others of which may be unlikely to occur, provides an equally compelling reason to
10 restrict research. Informed consent is clearly required when risks are more than minimal
11 to allow the individual to decide whether the potential harms are relevant and substantial.
12 Yet some of the harms mentioned in this chapter are not certain to occur and in many
13 cases are extremely unlikely to occur. Consideration may therefore be given to waiving
14 the requirement for consent in such cases.

15

16 *Objectionable, Unacceptable, or Questionable Research.* Individuals and groups may
17 also have an interest in the research uses to which the sample itself is put. Some people
18 may find the intended use of the knowledge gained to be objectionable. For example, for
19 religious or other reasons, some people may believe that their biological material should
20 not be used for contraceptive research or studies aimed at identifying individuals prone to
21 violence or other socially unacceptable behaviors. Or some individuals may consider it
22 objectionable that researchers could sell their samples to companies to make money.
23 Still others might have legitimate concerns if the materials were obtained in an unusual or
24 deceptive manner.

25

26 *Post-Mortem Uses of Biological Materials.* Many existing biological materials were
27 obtained from individuals who are long dead, and any specimen stored long enough will
28 outlast its source. It might be thought that once the source is dead, there are no interests
29 to protect; but this is not so, for a number of reasons. The decedent's family or other
30 loved ones may have an interest in what is done with the material, or members of the
31 source's ascriptive group may have an interest in what happens to it. Furthermore,

1 individuals can have interests that survive their own deaths. For example, persons
2 ordinarily have an interest in what happens to their children and grandchildren after they
3 themselves die and for this reason plan for the disposition of their estates. Similarly,
4 persons can have an interest in the uses to which their biological materials are put,
5 whether these uses occur before or after their deaths. This may be especially true if they
6 consider certain uses impermissible per se, from the perspective of their deepest, life-long
7 religious or ethical values. Additionally new information obtained about persons after
8 their deaths may affect the memories, perspectives, and relationships of family members
9 and others that have learned something for the first time. Even if, strictly speaking, the
10 dead have no interests to be protected, the living may want to establish policies to ensure
11 that some of these outcomes do not occur. Such policies could be viewed as reducing
12 living persons' worries and anxieties about what might happen after their deaths. Thus, a
13 policy of unrestricted access to stored specimens of deceased persons cannot be justified
14 on the grounds that no ethical issues are at stake. If people restrict use of their materials
15 while alive, those restrictions should also apply after their deaths. (Chapter 3 discusses
16 the regulatory perspective on this issue).

17

18 **Justice**

19

20 Some of the ethical concerns about the research use of human biological materials fall
21 under more than one general principle. For instance, justice may require certain
22 procedures to ensure fair participation in designing research protocols that may have a
23 negative impact on particular groups. Indeed, justice, along with the other two Belmont
24 principles, may and perhaps should be interpreted to include communities as well as
25 individuals. Just as beneficence may require attention to group harms and respect for
26 persons may require attending to their communities, so justice may also require attention
27 to procedures for group participation. In addition, as previously noted, the risks of
28 discrimination in health insurance and employment raise significant questions about just
29 institutions.

30

1 Other questions of justice also enter into ethical assessments of research uses of human
2 biological materials. For example, the weight that should be accorded to the societal
3 interest in benefits of applied biomedical science will depend in part upon how widely
4 these benefits are distributed, but also to whom. If there are gross inequalities in the
5 distribution of benefits, it is misleading to speak of the common interest in medical
6 progress. Consequently, the case for tolerating greater risks to the interests of sample
7 sources for the sake of the societal interest in medical progress is weakened if some
8 people, including some who provide the material, lack access to important health care
9 benefits because they cannot afford them. Nevertheless, if significant benefits of medical
10 progress accrue to a large number of people or people suffering from a rare, but
11 debilitating or lethal disease, a societal interest is relevant even if not all benefit or not all
12 benefit equally. This is particularly important, given that potential benefits may accrue to
13 future generations.

14
15 Some of the possible policies to protect sources of biological materials and others from
16 wrongs and harms will probably require increased expenditures for research. It is
17 plausible to argue that a just distribution of burdens of research requires the society to
18 invest those resources, where necessary and within limits, to reduce those wrongs and
19 harms, in part as a way to ensure public trust in research and to engender public
20 contributions of biological materials to important research endeavors.

21
22 *Justice, Respect for Persons, and the Commodification of the Body and Its Parts*

23
24 The distribution of the financial gains that may be produced through various uses of
25 human biological materials raises a number of concerns. Some individuals and groups
26 have sought to share in the profits that are generated by patentable biologic inventions in
27 whose development the use of their biological samples played a role. Perhaps the most
28 famous case is that of John Moore, who claimed a financial interest in the cell line that
29 was developed from tissue from his spleen. The California Supreme Court rejected
30 Moore's claim, and hence any claim to a portion of the profits derived from uses of the

1 cell line. However, it did affirm that the physicians who used his spleen tissue to develop
2 the cell line had a duty to disclose to him that they were going to do so.

3

4 The two parts of the ruling mark an important distinction between two questions: 1) is the
5 individual entitled to some or all of the profits gained from a product in whose
6 development his biological sample played a role? and 2) is the individual entitled to
7 disclosure of the fact that his biological sample may be used to develop a profitable item
8 and perhaps also allowed to refuse to allow such uses? These questions implicate two
9 distinct interests: the financial interest in profiting from the use of one's sample, and the
10 interest in determining whether one's tissue is used in a profit-generating endeavor.

11 Though less tangible than the financial interest, the second interest may be extremely
12 important for some individuals, for it may be rooted in their most fundamental
13 conceptions of distributive justice.

14

15 At this point it might be objected that it is misleading to refer only to the interest that
16 individuals have in a share of the profits derived from uses of their biological samples
17 and whether this interest should be recognized by a legal property right. According to
18 some, individuals have not only an interest, but a property right, because their tissues,
19 blood, and DNA are their property. Some moral philosophers have assumed or argued
20 that a person's body is her property, in the sense of a moral property right (Refs). The
21 model of the body as "property" stems from a claim of self-ownership, and seeks to
22 authorize individual persons to exercise control over the use and disposition of their body
23 and of body parts (Scott, 1981; Andrews, 1986). This view tends to treat the body as
24 incidental rather than intrinsic to personal identity, and allows the transfer body organs
25 and tissues to others by donation or sale without compromising the nature of the self.
26 These features make the property model very conducive to the scientific interest in body
27 tissue, with the proviso that the source of the tissue must consent. However, as the
28 Moore case shows, conflict can arise when, for example, a patient and a researcher assert
29 competing claims or "property rights" to excised body tissues. It should be noted as well
30 that non-instrumentalist views of the body are important in prominent cultural and
31 religious traditions in the United States. (Murray, 1996). The conflicting religious and

1 philosophical traditions that inform the discussion of the body as property make this a
2 topic to be more fully considered in another context. For this report it is sufficient to note
3 that these conflicting traditions form a background against which to consider the research
4 use of human biological materials.

5

6 **Conclusions**

7

8 Any ethically sound policy for research uses of human biological materials
9 must reflect a defensible balance of the ethical reasons that support greater control over
10 use and stronger protections, on the one hand, and those that support greater access to
11 samples for purposes of clinically beneficial research and/or clinical intervention, on the
12 other hand. These reasons vary in weight and impact depending on the extent of
13 identifiability of the sample source and on the probability and magnitude of various
14 wrongs and harms and of potential benefits.

15

16 The major ethical reasons that support greater control by sources and more
17 rigorous safeguards against harms and wrongs include avoiding discrimination in
18 insurance and employment, stigmatization, group harms, familial conflicts (including
19 those of survivors of the deceased), and uses that are objectionable to the source. As this
20 chapter indicates, it may be possible to avoid, or at least greatly reduce the risk of, some
21 of these harms and wrongs by developing, for instance, stronger protections of privacy
22 and confidentiality. Rather than assuming that there is a necessary conflict between
23 promoting important research and protecting tissue sources (and others) against various
24 wrongs and harms, policy makers should seek, with the widest possible public and
25 professional participation, to develop policies that avoid tradeoffs, while recognizing and
26 setting procedures to deal with situations that sometimes necessitate such tradeoffs,
27 especially those involving less weighty interests. The recommendations that follow in
28 the next chapter indicate some possible directions for policies that both promote
29 important research and provide sufficient safeguards for the rights and welfare of sources
30 of biological materials and their families, groups, and communities.

31

BOX 1

REMARKS BY THE PRESIDENT, The East Room, The White House, July 14, 1997

Thank you very much. You know, very often when I come into this room for an event like this to stand up for a cause I believe in, by the time it's my turn to speak there is nothing else to say. But that has never been more true than it is at this moment. Mary Jo, you were terrific, and we thank you. Thank you very much.

Secretary Shalala, Congresswoman Slaughter, Dr. Collins, the head of our genome project, Susan Blumenthal, the head of the Women's Health Office at HHS, ladies and gentlemen, thank you for being here. I want to say a special word of thanks, too, to Congresswoman Louise Slaughter. Both our families have known losses -- and hers very recently—and we appreciate her being here. I love to hear Louise Slaughter talk, with her beautiful southern accent. The first time I heard she was a congresswoman from New York, I thought it was a misstatement. And from my point of view, she's the only member of Congress from New York who speaks without an accent, and I like that.

The remarkable strides that we have seen in genetic research and testing are so important to every American family. Chances are, every family represented in this room in our lifetime will have a child, a grandchild, a cousin, a niece, a nephew somehow benefited from the work of the Human Genome Project, which seemed nothing more than an intellectual dream just a few years ago. And one of the things that we have to do is to make sure that every American family has a chance to benefit from it.

Secretary Shalala's report which she has issued -- it's a remarkable report, I commend it to all of you -- makes it clear that the scope of this era of discovery is truly astonishing. We are literally unlocking the mysteries of the human body, finding new and unprecedented ways of discovering not only the propensity for it to break down in certain ways or lead to certain forms of disease or human behavior, but also ways to prevent the worst consequences of our genetic structure.

And as with every kind of decision like this, there is always the possibility that what we learn can not only be used but can be misused. And in all of this era of scientific discovery, there is probably no greater promise for use or for misuse than in the area of genetic testing. Used in the right way, obviously it has the chances to save millions of lives and revolutionize health care. And I am proud of our aggressive support for the Human Genome Project.

But it's also clear that it is wrong for insurance companies to use genetic information to deny coverage. It's happened before. It happened in the 1970s with some African Americans who carried sickle cell anemia. And it can happen in many other ways. An enormous number -- percentage of American woman get breast cancer at some time during their lives. An enormous percentage of American men get prostate cancer at some time during their lives. There are other kinds of medical problems that occur with increasing frequency and that we'll see more and more as we grow older as a population.

And now, we see the consequences already of this kind of discrimination. It's wrong when someone avoids taking a test that could save a life just because they're so afraid that the genetic information will be used against them. And too many women today fear that that will happen when they decide to test or to not be tested to see if they carry the gene for breast cancer.

Now, this kind of discrimination is -- really it's more than wrong, it's a life-threatening abuse of a potentially life-saving discovery. And I can't help commenting that in the United States it is a direct consequence of the fact that we are the only advanced country in the world that has chosen to finance the health care of our citizens through a private insurance system that is completely optional and does not cover every one.

So that to be fair, the insurance companies themselves face some dilemmas that can only be fixed by the law, by a restatement of the public interest, so that none are treated differently from others if they make the decision to do what is morally right. And I think that's important to point out. I tried to fix it once and took

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1 a lot of criticism, but I'm not -- I'm not ashamed that I did. If I could fix it tomorrow, I would fix it
2 tomorrow, because this is not right.

3
4 But we have done what we could to try to, step by step, change this structure. A year ago, we took the first
5 step when Congress passed and I signed the Kennedy-Kassebaum bill, which prohibits group health plans
6 from using genetic information to deny coverage, and today my administration is sending legislation to
7 Congress that will ban all health plans, group and individual, from denying coverage or from raising
8 premiums on the basis of genetic tests. It will prohibit all health plans from disclosing genetic information
9 that could be misused by other insurers. But it will protect researchers' ability to make the best use of this
10 vitally important tool.

11
12 It builds on the solid foundation of Congresswoman Slaughter and Senator Olympia Snowe's bill, and I'm
13 pleased to say that Senator Frist from Tennessee and Senator Jeffords from Vermont have announced that
14 they will share our commitment and they will work with us to pass bipartisan legislation to ban
15 discrimination based on genetic tests.

16
17 This is an example of the step-by-step approach we are now taking that I will not be satisfied with until we
18 have made sure that every American family has the health care they need to thrive. We've already ensured
19 that a job change or an illness in the family doesn't mean automatically losing your health insurance.
20 We've made it easier for self-employed people to buy health insurance for their families. The balanced
21 budget agreement we have reached with the leaders of Congress that was voted for in its outline by
22 overwhelming majorities in both parties and both houses will extend care to millions and millions of
23 uninsured children. It will ensure, as Secretary Shalala said, that more older women can have
24 mammograms. It will protect Medicare and Medicaid.

25
26 But what we're here today to say is something very simple and yet profound. We cannot afford to let our
27 progress either in science or in extending health care to the American people to be undermined by the
28 misuse of what is a miracle of genetic testing. Americans should never have to choose between saving
29 their health insurance and taking tests that could save their lives. With these efforts, we will ensure at least
30 that no American ever has to make that choice again.

31
32 Thank you very much.

33 _____
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