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1 **Chapter 4**

2 **Ethical Perspectives on the Research Use of Human Biological Materials<sup>1</sup>**

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5 **INTRODUCTION**

6

7 The retrieval and use of human biological materials in diagnostic, therapeutic, research, and  
8 educational purposes represents a further development in the scientific study of the human body  
9 as a source of medical information. From this development arise a number of ethical issues for  
10 investigators, subjects, their families, and society. This chapter will focus primarily on more  
11 secular ethical considerations, with a particular emphasis on how various interests can be weighed  
12 in favor of more or less access to human biological materials. We adopt this more secular  
13 perspective because religious discussion of human organs and tissues has largely focused on  
14 donation for therapeutic purposes, with very little direct religious discussion of non-therapeutic  
15 research uses of human biological materials. It is useful, however, to describe the religious  
16 implications of research use of such materials in terms of: 1) religious attitudes to the human body  
17 and to organs, tissues, and cells removed from the body; and 2) religious discussion of modes of  
18 transfer of body parts, such as donations, offerings, sales, and abandonment. Where these issues  
19 arise, we discuss them in this text.

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<sup>1</sup>This chapter has been adapted from two commissioned papers for NBAC: Courtney Campbell, Religion and Tissue Samples, and Allen Buchanan, An Ethical Framework for Biological Samples Policy. The complete papers are

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2 More than 280 million human biological samples are currently stored in the United States,  
3 chiefly in pathology archives, blood banks, researchers' collections, and state public health  
4 department newborn screening facilities (see chapter 3). As noted above, some have been stored  
5 for decades, millions more will be gathered and stored in the next year, tens of millions more in  
6 the next decade. The individuals who are the sources of the samples are identifiable in some  
7 cases, not in others. Some samples were gathered during procedures (such as surgery) in which  
8 some form of informed consent was attained, some were not. Even where there was informed  
9 consent for the procedure that produced the sample, often there was no consent to some or any  
10 possible future uses of the sample. In many, perhaps most cases, individuals had no idea that their  
11 sample was being stored, nor any inkling that it might be used for a variety of research purposes,  
12 by a variety of individuals.

13

14 Genetic technology raises certain unique concerns. Any sample containing cells from any  
15 part of the body can be subjected to genetic analysis because every nucleus of every cell of the  
16 body (with the exception of red blood cells and reproductive cells) contains the complete genetic  
17 code of the person from whom the sample was taken. As we have already suggested, it is in part  
18 because of the seemingly limitless uses of genetic analysis? and the concerns that some possible  
19 uses evoke? that there is currently much interest in the ethical aspects of the practice of gathering  
20 and storing human biological samples that may be used for research.

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contained in Volume II of this report.

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2           The most obvious and tangible risk is the risk of insurance or employment discrimination  
3 on genetic grounds. There is also the risk of stigma or of adverse psychological reactions to  
4 information that the sample contains, given the special significance which genetic disorders has for  
5 some people. Nevertheless, as we shall see, the ethical issues raised by the practice of collecting  
6 biological samples do not depend, for the most part, on the possibility of genetic analysis, even if  
7 concern about “genetic privacy” may have fueled much of the current interest in the subject.

8

## 9 **FRAMING THE ETHICAL ISSUES**

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11           It is tempting to frame the complex set of issues involving biological samples as a simple  
12 conflict between the value of scientific research, on the one hand, and the rights to privacy and  
13 confidentiality, on the other. One problem with this formulation is that virtually all parties to the  
14 discussion acknowledge both the value of scientific research *and* the right to privacy and  
15 confidentiality.

16

17           Formulating the issues in terms of rights is unfortunate in two respects. First, rights  
18 language is rather black and white. There is a tendency to assume that if someone has a right to  
19 something, then that is the end of the matter. More specifically, there is a tendency to regard a  
20 clash between a mere value (such as scientific progress) and a right as an unequal one, whose  
21 resolution in favor of the right is clear and uncontroversial. Second, from the standpoint of

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1 ethical analysis, statements about what rights people have are better regarded as conclusions of  
2 complex strands of moral argument, rather than as starting points. It is necessary to dig beneath  
3 assertions about rights to privacy and confidentiality (or rights of individual autonomy) to unearth  
4 the morally legitimate interests that rights serve to protect.

5  
6         Declarations about rights can be used to derive further moral conclusions. For example, if  
7 an individual has a right to confidentiality, then it follows that substantial protections ought to be  
8 provided to limit the access of other persons to information about that individual. From this it  
9 follows that the mere fact that allowing others access to that information would contribute to  
10 some social good does not itself establish that they should have access. Before these conclusions  
11 can be drawn, however, it is necessary to establish the right to privacy. In that sense, rights-  
12 statements are conclusory even though, once established, they can serve as premises from which  
13 further moral conclusions can be drawn.

14  
15         Privacy and confidentiality are sometimes characterized as follows: privacy consists of  
16 appropriate limitations on access to the person as a physical being, especially to exposures of the  
17 body that are considered to be embarrassing or demeaning; confidentiality consists of appropriate  
18 limitations on access to information about a person. In order to ascertain what the appropriate  
19 limits are in both cases, and hence the scope of the rights to privacy and confidentiality, it is  
20 necessary to consider the various legitimate interests that are threatened by exposures of the body  
21 and by the dissemination of information about persons.

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## 2 **Rights as Protectors of Morally Important Interests**

3

4 Rights statements are assertions that certain interests are of such importance from a moral  
5 point of view that they deserve especially strong protections. The implication is that the interests  
6 in question are of such moral weight that they ought to be protected even if this means overriding  
7 what are otherwise typically taken to be powerful reasons for action. Thus even if the fact that  
8 doing something would maximize social utility is generally a very good reason for doing it, some  
9 interests are so important that they should be treated as being immune from calculations of utility.

10

11 Rights statements by themselves, being conclusions of moral arguments rather than  
12 arguments, at best only indicate the interests that deserve special protections. To clarify and  
13 justify a rights statement two things are needed: first, to identify the relevant interests; and  
14 second, to show why they are of such moral importance as to deserve the especially strong  
15 protections rights provide. In simplest terms, doing the latter means demonstrating that the  
16 interests in question play a significant role in determining whether individuals are able to  
17 flourish? to live the sort of lives that are appropriate for persons.

18

19 It is important to go beyond discussion of rights to the morally important interests that  
20 rights protect. If this is done it becomes clear that the ethical issues concerning biological  
21 materials involve a balancing of interests. This crucial fact is obscured if we begin with talk about

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1 rights to privacy and confidentiality (or rights to freedom of scientific inquiry, for that matter),  
2 because assertions about rights presuppose that the proper balancing of interests has already been  
3 achieved. Once it is understood that rights serve to protect interests, rights talk becomes less  
4 mystifying and can be seen as a shorthand for assertions about what the moral priorities are,  
5 assertions grounded ultimately in the conditions of human flourishing.

6  
7 This is not to say that there is no such thing as a right to privacy or to confidentiality.  
8 There are legal rights that go by these names. It can even be said that there are moral rights to  
9 privacy and confidentiality, as long as it is recognized that this merely presumes that certain  
10 interests ought to receive special protections through safeguarding privacy and confidentiality and  
11 that whatever the proper balance of conflicting interests turns out to be it must reflect this  
12 presumption. Invoking rights to privacy and confidentiality reveals nothing about the proper  
13 scope and limits of those protections.

14  
15 To better ascertain the scope and limits of such protection it is useful to catalogue the two  
16 sets of interests that can come into conflict: those that weigh in favor of restricting access to  
17 biological samples (and hence to the information they contain) and in favor of giving the source of  
18 the sample more control over what is done with the sample; and those that weigh in favor of  
19 wider access to the sample, even though this means less control over its uses by the source. After  
20 cataloguing the various interests on both sides of the ledger, the adequacy of the requirement of  
21 informed consent can be evaluated as a means of achieving an appropriate balance of interests.

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1 The Commission recognizes, however, that it is a profound mistake to proceed as if some version  
2 of an informed consent requirement by itself can provide protection for all the legitimate interests  
3 at stake in the practice of gathering and using biological samples. Instead, what is needed is an  
4 institutional division of labor in which informed consent plays an important but limited role.  
5 Moreover, attempting to safeguard against all possible harms to those who provide samples by an  
6 elaborate informed consent requirement is not only doomed to failure but would also be  
7 unconscionably costly and an excessive constraint on socially valuable scientific research.

8

### 9 **Interests, Well Being, and Harms**

10

11 Put most simply, an interest is an ingredient in someone's well being. If your interest is  
12 advanced, then, other things being equal, you are better off; if your interest suffers a setback,  
13 then, to that extent you are worse off (Feinberg, 1984). Peoples' interests vary widely, but there  
14 are some interests that are basic to all persons. The doctrine of human rights can best be  
15 understood as an attempt to identify these fundamental universal interests and to proclaim that  
16 they deserve the most stringent protections.

17

18 Ethicists often distinguish between welfare interests and ulterior interests (Feinberg, *ibid*).  
19 Welfare interests include access to food and shelter, as well as physical security, liberty of action,  
20 and access to information. Ulterior interests include the various ends that individuals give high  
21 priority to as they arrange their lives, choose an occupation, and plan for the future. Welfare

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1 interests are a very important ingredient in a person's life because if they are not secured the  
2 person will not be able to pursue ulterior ends. Nevertheless, once a person's welfare interests are  
3 secured, the pursuit of his ulterior ends becomes not only possible, but also extremely important.  
4 The distinction between welfare interests and ulterior interests helps illuminate the full range of  
5 interests at stake in choosing a policy for regulating the gathering and uses of biological samples.

6  
7         Given this understanding of what an interest is, a harm can be defined as a setback to an  
8 interest (Feinberg, *ibid*). NBAC focused on the possible harms that persons can suffer if others  
9 gain information from their biological samples or use those samples in various ways. In doing so,  
10 the important moral concerns that lie behind the notions of privacy and confidentiality are brought  
11 to the fore.

12

### 13 **Biological Sample Information**

14

15         Gathering information about an individual through the taking of a medical history or by  
16 interpreting the inscriptions on an electrocardiogram may have a different significance for the  
17 individual or others than biopsying a piece of tissue or drawing blood. But from the standpoint of  
18 many of the interests at stake in the way biological samples are used, what is most important is the  
19 information the sample can yield, not the physical embodiment of the information.

20

21         As technology advances, automated analysis of samples (for genetic and other

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1 information) may reduce the need to store samples. Nevertheless, most of the ethical issues  
2 would remain, because they are related to the uses of the information derived from the samples,  
3 not the sample itself. For this reason, the term “biological sample information” is used to cover  
4 both the sample itself and the information that can be extracted from it, noting that in most cases  
5 it is the information that matters, once the sample has been taken.

6

7 **ELEVEN INTERESTS THAT WEIGH IN FAVOR OF RESTRICTED ACCESS AND SUBSTANTIAL CONTROL**  
8 **BY THE SOURCE OF THE SAMPLE**

9

10 The purpose of this and the following section is to list those interests that would seem to weigh in  
11 favor of restricted or wider access to samples respectively. The interests are not lexically ordered,  
12 but they are grouped to reflect individual and societal interests. Although this first section  
13 identifies eleven interests weighing in favor of restricted access, and the following section  
14 identifies eight interests weighing in favor of fewer restrictions, this presentation does not imply  
15 that since more interests are found in the former than the latter, that a policy of greater restriction  
16 follows. Interests need to be considered individually and as groups.

17

18 **1. Avoiding Insurance and Employment Discrimination**

19

20 Given current social and institutional arrangements, persons known to have health

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1 problems may be vulnerable to insurance and employment discrimination<sup>2</sup>, regardless of whether  
2 they have genetic disorders, genetic susceptibilities to disease, or other illnesses. Moreover, being  
3 listed in a tumor registry or replying truthfully to questions about one's family medical history may  
4 be just as risky as having a positive test for a genetic disorder in one's medical records.

5  
6 The actual extent of insurance and employment discrimination on genetic grounds is a  
7 matter of speculation because most of the evidence comes from surveys in which individuals self  
8 report discrimination, with little or no independent check on the accuracy of their perceptions  
9 (Billings, 1992). Still some evidence has been presented (Lapham, 1996). Moreover, the risk  
10 exists only for insurance policies whose issuance is conditional on medical underwriting, and most  
11 Americans who have private health insurance get it through large group policies in which there is  
12 no medical underwriting. Nevertheless, it is clear that insurance and employment discrimination  
13 do occur and that when they occur the results can be devastating for the individual.

14  
15 It is also important to emphasize that the risk of discrimination is not an inevitable effect  
16 of the existence of information about illness or susceptibility: it is an artifact of a particular  
17 institution, namely, a private insurance market in which most medical insurance is employment-  
18 based and in which private insurers compete in part by attempting to avoid insuring costly (and  
19 therefore sick) individuals. If this institution were abolished or modified in certain ways so as to  
20 reduce the risk of discrimination, then to that extent the weight of the interest in avoiding

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<sup>2</sup> Note prejudicial character of the term “discrimination” in this context.

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1 discrimination would diminish, and with it the case for restricting access to biological sample  
2 information in order to protect the interest in avoiding discrimination. (It is also important to  
3 emphasize, however, that discrimination in life insurance and disability insurance also occurs in  
4 other countries, which do not rely on private insurance for health care as heavily as does the  
5 United States. [Knoppers, 97] )

6  
7 From this it follows that in a society like ours, in which there is a powerful institution that  
8 poses a significant threat of discrimination, greater restrictions on access to biological sample  
9 information will be needed, other things being equal, than in a society in which different  
10 institutions for financing health care eliminate the possibility of discrimination. If federal and state  
11 laws prohibiting insurance and employment discrimination are passed and effectively implemented,  
12 the balance between interests that weigh in favor of more restricted access and greater source  
13 control and those that weigh in favor of freer access and more permissive uses of biological  
14 samples will shift accordingly. Therefore, whatever policy is now developed must be subject to  
15 revision in the future.

16

## 17 **2. Avoiding Stigmatization**

18

19 Even if an individual is not denied insurance or employment, he or she may suffer the harm  
20 of stigmatization. Although there is an unfortunate tendency to focus only on the stigmatization  
21 that results from being identified as having a genetic disorder, other types of illness can be equally

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1 or even more stigmatizing (e.g., sexually transmitted diseases, disfiguring diseases, and cancer).

2

3 Stigmatization is closely related to discrimination; indeed it can be argued that it is a  
4 species of discrimination. Like discrimination, it is a form of exclusion by labeling. In the case of  
5 stigmatization, however, there is usually at least an intimation of unwholesomeness, blame, or  
6 taint. Some, but not all forms of discrimination include this feature.

7

8 Perhaps the most familiar type of stigmatization is that which is imposed on an individual  
9 from without, by the judgments and perceptions of other individuals. However, because  
10 individuals are so often deeply influenced by the attitudes of their peers, they may internalize  
11 stigmatization.

12

13 The weight that should be accorded to the interest in avoiding insurance or employment  
14 discrimination varies with the magnitude of the risk, and hence with the institutional arrangements  
15 that either magnify or diminish that risk. Similarly, the weight that should be accorded to the  
16 interest in avoiding stigmatization varies with cultural attitudes toward disease. For instance, to  
17 the extent that the public becomes better educated about the nature (and universal prevalence) of  
18 genetic susceptibility to disease, the risk of stigmatization on genetic grounds may diminish. And  
19 as with insurance and employment discrimination, the actual risk of stigmatization associated with  
20 various types of information contained in biological samples, as opposed to the mere possibility  
21 that stigmatization, is unknown.

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### **3. Avoiding Ascriptive (Group Identity-Based Harms)**

Closely related to discrimination and stigmatization is another potential harm that individuals may suffer because of perceived links between medical information about them contained in a biological sample and what may be called their ascriptive (or group-based) identity. A concrete example will make this concept clearer.

African Americans typically suffer certain harms because they are identified as African Americans: others often perceive African American individuals through the distorted lens of negative racial stereotypes. The harm of negative racial stereotyping is a harm to individuals, but it befalls individuals because of their ascriptive group identity. The term ascriptive here indicates that the identity in question is assigned by others, independent of the choice of the individual thus identified.

Individuals who are vulnerable to ascriptive-identity harms have a special interest in avoiding situations in which information obtainable from their biological samples may contribute to the reinforcement of harmful group stereotypes, not only because they themselves may be harmed but also because they may wish to avoid harm to other members of their ascriptive group. For instance, genetic information gleaned from biological samples might be used in research on the role of genes in criminal behavior or in intelligence. In the past such research has sometimes both

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1 embodied and been taken to validate negative racial stereotypes.

2

#### 3 **4. Avoiding Familial Conflict**

4

5 In some instances, biological sample information, like other medical information, may be  
6 a source of intra-familial conflict. For example, genetic analysis of a blood sample may reveal that  
7 the husband is not the father of the child. Or, in some cultures, if a family finds out that the  
8 prospective spouse of one of their members has a genetic disorder, they may attempt to prevent  
9 the marriage from taking place. Regardless of whether the beliefs on which they are based are  
10 rooted in mistaken views about genetics or indefensible assumptions about responsibility for  
11 disease, the conflicts they can generate and the resulting harms are quite real.

12

#### 13 **5. Avoiding Uses of Biological Samples that the Source Regards as Impermissible**

14

15 Individuals and communities can also have an interest in the uses to which the sample itself  
16 is put. For example, for religious or other reasons, some people may believe that DNA from  
17 samples should not be used for producing human beings by cloning because they believe that  
18 human cloning is wrong *per se*; or they may simply not want their DNA to be used for this  
19 purpose. Or, as Courtney Campbell has argued, the reflection of religious scholars and  
20 communities on the status of body parts has been prompted by the necessity to confront practical  
21 questions in personal and public health and in communal life, such as justifications for surgery,

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1 autopsies, organ donation, or burial. Scientific and research interest in parts of the body can  
2 sometimes conflict with religious values about bodily integrity. Indeed, E. Richard Gold cites the  
3 “disparate claims of scientific investigation and religious belief on the body” as the exemplary case  
4 of uneven values regarding the body. According to Gold, “The body, from a scientific viewpoint,  
5 is a source of knowledge of physical development, aging, and disease. From a religious  
6 perspective, the body is understood as a sacred object, being created in the image of God. . . The  
7 scientist values the body instrumentally, as a means to acquire knowledge; the believer values the  
8 body intrinsically, for being an image of God” (Gold, 1996).

9  
10         There are two factors that make it difficult to know how much weight this interest ought  
11 to be given in designing an ethically sound and feasible system for regulating practices concerning  
12 the uses of biological samples. First, no one knows at present the full range of possible uses for  
13 biological samples in the future; the science of molecular biology and genetic technology is  
14 evolving rapidly. Consequently, at some point in the future someone's biological sample might be  
15 used in ways that he or she finds inherently wrong. The uncertainty here is not just a function of  
16 ignorance of the technical possibilities; future cultural attitudes and regulations (e.g., concerning  
17 experiments on human subjects) could change and constrain possible uses of biological samples,  
18 independently of any control that might be exercised by the individual who is the source of the  
19 sample.

20  
21         Second, in some cases, individuals’ fears about how their tissue might be used in the

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1 future may be based on grossly mistaken assumptions. For example, at least part of the negative  
2 response to the possibilities of producing humans by cloning seems to be based on the fallacies of  
3 genetic determinism and genetic reductionism (the false assumption that a genetic identity is  
4 predetermined personal identity). In some cases the preference that one's biological sample not  
5 be used for certain purposes may not be based on false factual assumptions and may reflect one's  
6 stable values and commitments. Here one does have an interest in avoiding such uses of one's  
7 biological sample. Of course, respect for autonomy may argue for giving some weight to an  
8 individual's preferences even when they are based on patently false beliefs; but nonetheless, the  
9 fact that a preference is based on patently false beliefs should surely reduce its moral weight, other  
10 things being equal. To put the same point differently: people can be mistaken about what is in  
11 their interest, and the strongest ground for devising constraints on the use of stored tissue is that  
12 doing so is needed to protect important interests, not to indulge individual's clearly mistaken  
13 perceptions about their interests. What does seem likely is that in some cases what we would  
14 now regard as wrong or at least problematic we may regard as acceptable in the future, when  
15 society has changed and we have changed with it.

16

## 17 **6. Avoiding Dignatory Harms**

18

19 Each person has an interest in being treated as a person, as a moral agent with unique  
20 values, preferences, commitments, and conceptions of the good. Part of the moral justification for  
21 the requirement of informed consent is to ensure that patients and research subjects are treated

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1 respectfully as agents, not as passive objects to be used for the ends of others.

2

3 First and foremost, however, the requirement of informed consent protects individuals  
4 from nonconsensual invasions of their bodies. Because the right of informed consent, which  
5 includes the right to refuse treatment, allows the individual to decide whether the risk of these  
6 harms is worth taking, it can also protect individuals from other tangible harms that may result  
7 from the bodily invasion, if the individual refuses to give consent.

8

9 It is important to note that these harms are not restricted to the minimal harms that might  
10 occur from techniques such as drawing blood or swabbing cells from the inside of the cheek. The  
11 point, rather, is that if one allows others access to one's body for these purposes one is thereby in  
12 a position of vulnerability to other unwanted and more dangerous intrusions. For this reason it is  
13 somewhat misleading to say that the only physical harm from which one is protected by informed  
14 consent for a simple procedure such as drawing blood is the extremely remote possibility of harm  
15 from the needle stick (beyond the unpleasant momentary sensation of the pricking itself).

16

17 Even if informed consent was originally primarily a protection against physical harm, it has  
18 come to be used as protection against a broad range of nonphysical harms lumped under the  
19 heading "psychosocial." Thus, for example, Institutional Review Boards strive to ensure that  
20 informed consent procedures for psychological or other social science research protect individuals  
21 from being deceived and manipulated in ways that are demeaning or threatening to a person's

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1 sense of self worth or that treat that person as a mere means.

2

3 A strong case can be made that current practices concerning biological samples often fail  
4 to treat persons with due respect because they systematically mislead as to why samples are being  
5 taken and to what uses they will be put. It is true that the person who draws the blood sample  
6 may not know that the sample will be stored indefinitely and may be used in any number of ways  
7 in the future and hence may have no intention to mislead. Nevertheless, the institutionalized  
8 practice of storing biological samples for future uses is one for which those who control the  
9 practice are responsible, and this practice, as we have seen, often does not inform sample sources  
10 about what may happen to the sample. Given the various interests already listed above, a practice  
11 that is misleading in this way fails to show proper respect to sample sources.

12

13 The most obvious way to correct this defect is to modify the practice by informing  
14 individuals that their biological samples will or may be used for a wide range of purposes where  
15 this is not already done. Whether or not in addition to such disclosure, specific or general consent  
16 is required in order to show proper respect for sample sources is a question taken up below. The  
17 main point, however, is that informed consent should not be assumed to be the only means for  
18 protecting individuals against the dignitary harm of being deceived or misled.

19

20 Another way of understanding the type of dignitary harm described here evolves from the  
21 different ways of assessing the moral status of the body. There are different ways of assessing

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1 the theological and moral status of the body and of body organs and tissues depending on the  
2 “place” of the organs or tissues, that is: 1) intrinsic to self-identity (e.g., heart) or incidental; 2)  
3 visible (e.g., eyes, skin) or hidden (e.g., kidney); and 3) integrated (e.g., circulating blood) or dis-  
4 incorporated (e.g., bodily excretions). In general, it may be claimed that the more a human  
5 biological material possesses the former of these characteristics, the more its retrieval and use for  
6 biomedical research purposes may present theological and ethical questions. Put another way,  
7 western religious thought on the body begins with a strong presumption that the status of the  
8 body as a whole is greater than the sum of its parts. Body organs and tissues, moreover, contain  
9 potent symbolic significance when considered as part of the bodily whole (Vlahos, 1979). Yet, as  
10 noted above, organs and tissues when considered in isolation from the rest of the body seem a  
11 source of revulsion and stigma. The relevant question is what religious significance should be  
12 attributed in particular to body tissue that may be stored and used for purposes of medical  
13 science.

14

## 15 **7. Avoiding Invasions of Privacy**

16

17 People have an interest in not being subjected to unnecessary exposure of the body to the  
18 view of others and in not having embarrassing or intimate facts about themselves disclosed,  
19 independently of whether such exposure or disclosure threatens other interests they may have or  
20 produces other harms. For example, one has an interest in others not knowing certain intimate  
21 information about one’s reproductive history and in not having one’s body unnecessarily exposed

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1 to view, even if these breaches of privacy cause no tangible harm, for example, by making one the  
2 subject of disparaging gossip.

3  
4 This interest, which might be called the interest in privacy *per se*, is distinguishable from  
5 the various other interests catalogued above that serve to ground a right to privacy. It is closely  
6 related to the interest in avoiding dignitary harms, since in most if not all cultures, some modes of  
7 exposing the body, in some contexts, are thought to be undignified and demeaning and some  
8 intimate information is thought to be embarrassing.

9  
10 It is this interest in privacy and confidentiality *per se* that is invoked when a patient or  
11 subject complains that the setting in which he or she is examined or in which he or she answers  
12 questions about his or her personal medical history is “too public” or “lacks privacy.” Unlike  
13 some of the interests already noted, the interest in privacy *per se*, is at stake as much in the  
14 process by which the sample is collected as in what happens to the sample after collection.

## 15 16 **8. Avoiding Disclosures of Confidential Information**

17  
18 For the most part, once the biological sample is removed from the body, it is the interest in  
19 confidentiality, rather than the interest in privacy, that is at issue. The term “confidentiality” means  
20 “with trust”; preserving the confidentiality implies keeping confidences, of confiding in those we  
21 trust. With some risk of over-simplifying, confidentiality may be thought of as a kind of second

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1 best to privacy. In some contexts, medical and otherwise, persons must expose themselves to the  
2 gaze of others or divulge sensitive information to them in order to gain certain benefits, and the  
3 best they can hope for is that there will be no unnecessary or otherwise inappropriate viewing or  
4 disclosure to others, and that those who gain this intimate knowledge of ourselves will not use it  
5 to their detriment.

6  
7 People have an interest in confidentiality, in being able to trust that access to their samples  
8 and to the information they contain will be appropriately limited. But what counts as an  
9 appropriate limitation will depend upon a complex weighing of conflicting legitimate interests.  
10 Thus, simplistic statements about the right to confidentiality (e.g., that access to personal  
11 information can be based on a “need to know”) are not particularly helpful. To say that there is  
12 such a right is simply to assert that the interest in limiting intimate exposures is a high moral  
13 priority, and as such warrants special protections; it does not tell us what the contours of the right  
14 are.

## 15 16 **9. Surviving Interests**

17  
18 Many existing biological samples were taken from individuals who are long dead, and if  
19 any sample is stored long enough it will outlast its source. It might be thought that once the  
20 source is dead, there are no interests to protect; but this is not so, for two reasons. First, the  
21 deceased source’s family or other loved ones may have an interest in what is done with the

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1 sample, or members of the source's ascriptive group may have an interest in what happens to it  
2 (if, for example, research were done on the sample that contributed to racial stereotyping).

3  
4 Second, persons can have interests that survive their own deaths. For example, persons  
5 ordinarily have an interest in what happens to their children and grandchildren after they  
6 themselves die and for this reason plan for the disposition of their estates. Similarly, one can have  
7 an interest in the uses to which one's biological sample are put, whether these uses occur before  
8 or after one's death. This is especially true if certain uses would be considered impermissible *per*  
9 *se*, from the perspective of one's deepest, life-long religious or ethical values. From this it follows  
10 that if a policy of unrestricted access to samples of deceased persons is to be justified it cannot be  
11 justified on the grounds that no interests are at stake. In the same way, this also argues that if a  
12 person restricted use of his or her sample while alive, these restrictions should also apply after the  
13 person is deceased. (In the next chapter, we discuss the regulatory perspective on this issue).

14

## 15 **10. The "Autonomy" Interest in Control**

16

17 It might be said that, independent of the functions of informed consent, a proper  
18 consideration of the individual's autonomy weighs in favor of allowing the individual maximal  
19 control over his or her sample, and that this in turn requires specific consent for particular uses of  
20 the sample.

21

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1           However, it is a mistake to assume that increasing a person's range of choices will thereby  
2 enhance autonomy. In some cases, increasing the range of choices may actually diminish a  
3 person's ability to act autonomously, especially when the information needed for a responsible  
4 choice is not available (Dworkin, 19\_\_ ). Furthermore, it is also a mistake to assume that if an  
5 individual is not allowed to exercise choice over some matter his or her right to autonomy is  
6 infringed. Not every possible choice counts so far as autonomy is concerned. In general, whether  
7 the ability to make a choice represents a legitimate autonomy interest (much less an interest that  
8 deserves the protection that rights accord) will depend upon how that choice is related to the  
9 individuals other interests, to one's conception of oneself and of what is important.

10

11           Consequently, what might be referred to guardedly as the "interest in autonomy *per se*"  
12 might more accurately be called the interest in choice, to signal that not all choices bear  
13 importantly on an individual's autonomy. Once it is understood that the mere ability to have a  
14 choice over the disposition of one's biological sample is not the same as a legitimate interest in or  
15 a right to autonomy, it becomes difficult to require specific consent on the ground that it enhances  
16 individual autonomy, especially given the weight of the interests that weigh against the imposition  
17 of such an onerous and costly requirement.

18

## 19 **11. Concerns About Profits, Distributive Justice, and "Commercialization"**

20

21           A cluster of interests alternatively weigh in favor of restricting access to or uses of

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1 biological sample information, or concern the distribution of the financial gains that may be  
2 produced through the uses of samples.

3  
4 Some individuals and groups have sought to share in the profits that are generated by  
5 patentable biologic inventions in whose development the use of their biological samples played a  
6 role. Perhaps the most famous case is that of John Moore, who claimed ownership of a cell line  
7 that was developed from tissue from his spleen.<sup>3</sup> The California Supreme Court rejected Moore's  
8 claim of ownership, and hence any claim to a portion of the profits derived from uses of the cell  
9 line. However, it did affirm that the physicians who used his spleen tissue to develop the cell line  
10 had a duty to disclose to him that they were going to do so.

11  
12 The two parts of the ruling mark an important distinction between two questions: 1) is the  
13 individual entitled to some or all of the profits gained from a product in whose development his  
14 biological sample played a role? and 2) is the individual entitled to disclosure of the fact that his  
15 biological sample may be used to develop a profitable item and perhaps also allowed to refuse to  
16 allow such uses? These questions implicate two distinct interests: the financial interest in  
17 profiting from the use of one's sample, and the interest in determining whether one's tissue is used  
18 in a profit-generating endeavor. Though less tangible than the financial interest, the second  
19 interest may be extremely important for some individuals, for it may be rooted in their most  
20 fundamental values about distributive justice.

---

<sup>3</sup> Moore vs. The Regents of the University of California et al, 793 P.2d 479 (Cal. 1990).

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1

2           Strictly on economic grounds, there may be a case for not having a property rights system  
3 that gives individuals like Moore a legal right to a share of the profits of whatever products are  
4 developed from processes in which his sample played some role. For one thing, most of the  
5 products developed from biological samples are not uniquely dependent upon the particular  
6 sample from which they are developed. (What was needed were human spleen cells from a person  
7 with a certain type of cancer, not necessarily Moore's spleen cells). And given the well-known  
8 relationship between supply and demand, this means that in most cases no particular individual's  
9 biological material will be valuable enough to generate a claim to a significant share of the profits  
10 and to justify the special property laws that would be needed to secure that claim.

11

12           However, there may be some cases where something profitable can be developed only  
13 through the use of a rather rare genetic mutation. (For example, it has been reported that there is  
14 a family in Northern Italy that has a mutation that protects against atherosclerosis, an "anti-  
15 cholesterol gene." Or, if it turns out that a small minority of the population has a natural  
16 immunity to HIV infection, this characteristic might be extremely valuable for the development of  
17 an HIV vaccine). Whether or not it would be desirable to recognize a legal property right in such  
18 cases will depend upon the proper balancing of a complex array of factors and above all upon  
19 whether there is reason to believe that individuals with extremely valuable genes will lack  
20 sufficient incentive to allow them to be used for producing significant benefits for large numbers  
21 of people without the sort of financial reward which such a property right would confer.

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1  
2           At this point it might be objected that it is misleading to talk only of the interest that  
3 individuals have in a share of the profits derived from uses of their biological samples and of  
4 whether this interest should be recognized by a legal property right: individuals have not only an  
5 interest, but a property right, because their tissues, blood, and DNA are their property if anything  
6 is. And indeed some moral philosophers have assumed or argued that a person's body is her  
7 property, in the sense of a moral property right.<sup>4</sup> The model of the body as “property” stems from  
8 a claim of self-ownership, and seeks to authorize the individual person with control over the use  
9 and disposition of their body and of body parts (Scott, 1981; Andrews, 1986). This view tends to  
10 treat the body as incidental rather than intrinsic to personal identity; the body as a totality is  
11 distinct from the self, and body organs and tissues can be transferred or alienated to others  
12 without compromising the nature of the self. These features make the property model very  
13 conducive to the scientific interest in body tissue; with the proviso that informed consent is  
14 obtained from the person. However, conflict can arise when, for example, a patient and a  
15 researcher assert competing claims or “property rights” to excised body tissues, as the Moore  
16 cases shows.

17  
18           Hence the statement that an individual has a moral property right to his or her biological  
19 material is to be understood as shorthand for the assertion that there are morally legitimate  
20 interests that require special protections and that these protections can best be achieved by

---

<sup>4</sup> Add references

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1 allowing the individual control over the uses to which the sample is put. But of course there are  
2 many possible modes and degrees of control. Only by weighing the legitimate interests that speak  
3 in favor of various forms of sample source control against the morally legitimate interests that  
4 speak in favor of allowing others freer access and a wider range of possible uses of samples, can  
5 one decide the types of controls that are morally preferable. At this stage of the analysis the most  
6 that can be said is that a person may have a legitimate property interest in the distributive effects  
7 of the uses of his or her biological sample. At present not enough is known about the probable  
8 future value of particular configurations of genes to determine what sort of legal property rights in  
9 them would make moral and economic sense.

10

11 We note that the scientific and property perspectives assume the legitimacy of the use of  
12 body tissue, and direct attention to the avoidance of abuse. By contrast, the theological emphasis  
13 on the embodied self and bodily integrity entails the need to articulate an argument that justifies  
14 use of the body.

15

16

17 **EIGHT INTERESTS THAT WEIGH IN FAVOR OF FEWER RESTRICTIONS ON ACCESS AND LESS**  
18 **SAMPLE SOURCE CONTROL**

19

20 **1. Preventing Disease and Disability for Identifiable Individuals, Present and Future**

21

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1           In addition to contributing to the prevention of harms to large numbers of people through  
2 advances in the prevention and treatment of disease and disability, freer access to biological  
3 samples can make it possible to intervene directly to prevent harm to identifiable individuals in  
4 some instances. For example, if the source of a sample can be identified, then he or she can  
5 benefit from successful treatment breakthroughs. Or, if research shows that persons with a  
6 particular genetic makeup have a high susceptibility to some serious disease, then it may be  
7 possible to intervene earlier with better results, if those individuals can be identified from stored  
8 samples. In some cases the individual who benefits may be the offspring of the sample source as,  
9 for example, when a genetic disorder that can be successfully treated can be predicted on the basis  
10 of information contained in the sample; in other cases it may be a sibling or other relative.

11

## 12 **2. Interests in Reproductive Freedoms**

13

14           Individuals have several important reproductive interests: in being able to have children if  
15 they wish, and in having control over when they have children and how many children they have.  
16 They also have an interest in exercising some control over the characteristics of the child they  
17 have, for the sake of the child himself or herself, but also in part because these characteristics may  
18 affect their own well-being and that of their other children.

19

20           Few would question that prospective parents have a legitimate interest in whether the  
21 child they bring into being is spared avoidable diseases or disabilities. Whether, or to what extent

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1 they also have a legitimate interest in determining other characteristics, such as height, eye-color,  
2 or cognitive abilities, is more controversial. But in general, the more their control over the  
3 characteristics of the child can be justified by appeal to the interests of the child his or herself,  
4 rather than simply to the interests or preferences of the parents, the stronger the case for  
5 protecting the parents' interest in exercising this control.<sup>5</sup>

6  
7 In coming years, research on biological samples will most likely increase dramatically the  
8 range of reproductive alternatives available to people, thereby furthering in significant ways their  
9 interests in various reproductive freedoms. Not all of the interests served will be “medical”  
10 interests, in the sense of interests in the prevention or cure of diseases, but in many cases they will  
11 be important interests nonetheless. Research on biological samples not only serves peoples’  
12 welfare interests by preventing disease and disability, it may also serve their ulterior interests, so  
13 far as these include a conception of whether to have children, when to have them, how many to  
14 have, and even perhaps their characteristics.

### 16 **3. The Interest in Enhancement through Biotechnology**

17  
18 Until recently, with few exceptions, health care has been concerned primarily with  
19 preventing or ameliorating harms caused by disease and disability. In the future, however, genetic  
20 interventions as well as developments in psychopharmacology may make possible enhancements

---

<sup>5</sup> See Genes and the Just Society, especially Chapter Five.

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1 of normal human functioning. For example, it may eventually become possible to manipulate  
2 genetic material so as to improve some aspects of cognitive functioning, or to augment the normal  
3 human immune system.<sup>6</sup> Whether or to what extent there will be substantial societal interest in  
4 enhancements made possible by the growth of scientific knowledge will depend not only on  
5 whether these enhancements are really beneficial, all things considered, but also on whether they  
6 will be widely available.

7

#### 8 **4. Interests in Altruism, Contributing to General Social Welfare, and the Research**

##### 9 **Enterprise**

10

11 Form some individuals, or communities, an interest may exist in participating in research  
12 using human biological materials. The interest may be related to the feelings of altruism or  
13 general social benevolence that may motivate volunteers generally in research, or to other more  
14 direct motivations such as contributing to the particular welfare of a group for whom a disease  
15 seems particularly prevalent. This perspective was reflected in the mini-hearings convened by the  
16 Commission.<sup>7</sup>

17

18 The general interest in contributing to social welfare does have a theological parallel. For

---

<sup>6</sup> For an in-depth examination of the ethical issues concerning genetic enhancement, see Allen Buchanan, Dan W. Brock, Norman Daniels, and Daniel I. Wikler, Genes and the Just Society: Genetic Intervention in the Shadow of Eugenics, especially Chapter Four, need rest of ref.

<sup>7</sup> [Cite mini-hearing report]

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1 example, in religious thought the most common justifying argument for overriding the  
2 presumption in favor of bodily integrity and wholeness is found in the “donation paradigm.”

3  
4 With very few exceptions religious thought on the body and its use within medicine has  
5 presupposed a context within which organs and tissues are donated for therapeutic purposes of  
6 healing, restoring, or saving life. This moral presumption is emphasized through the language of  
7 “gift,” “altruism,” or “sacrifice,” on the part of the donor and that of “benefits” for recipients.

8 Four principal features can describe the donation paradigm:

9  
10 1) ***Altruistic intent.*** The intent of the donor of an organ or tissue is structured by gift-  
11 giving to specific beneficiaries or recipients, such as persons on a waiting list for a transplant  
12 (although the identity of such persons may be veiled from the donor).

13  
14 2) ***Therapeutic expectation.*** The expectation for the gift of the body is that it will offer a  
15 pronounced therapeutic prospect for the recipient. The provision of a needed organ or tissue  
16 should offer substantial benefits to the individual beneficiary, whether as enhanced quality of life,  
17 or the preserving of life itself.

18  
19 3) ***Re-incorporation.*** Body tissue that has been retrieved from the donor, or dis-  
20 incorporated, should in most circumstances be “re-incorporated” within the body of the recipient.  
21 Some religious practices and rituals require burial of removed body parts, or re-incorporation in

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1 the earth. This is particularly the case with body parts that have an identifiable human form: In  
2 Jewish thought body parts composed of “flesh, sinew, and bones,” such as limbs, should under  
3 most circumstances be buried. Roman Catholic tradition distinguishes major from minor parts of  
4 the body in a manner similar to Jewish thought. Major parts of the body are those that retain their  
5 “human quality” following excision (a limb) and should be buried (Childress, 1989; 1995). Such  
6 concerns may reflect the importance of these visible body parts for self-identity.

7

8       4) ***Recipient Responsibilities.*** The gift of the body also carries with it certain  
9 responsibilities on the part of the recipient, responsibilities that are embedded in everyday  
10 practices of sharing and gift-giving (Camenisch, 1981, Murray, 1987). These include a sentiment  
11 of gratitude towards the gift-giver, or towards the institutional structure that mediates the gift  
12 transfer. Gratitude should also be enacted in the actions and conduct of the recipient by which he  
13 or she makes grateful use of the gift. In addition, a gift induces a responsibility of reciprocity.

14

15       The donation paradigm as delineated above thus provides a religious ground or  
16 justification for medical use of human biological materials. It is limited, however, for the most  
17 part to medical practices of transplantation or transfusion, that is, those practices that promise  
18 some form of therapeutic outcome from the gift. More discussion is needed on whether the  
19 donation paradigm can accommodate non-therapeutic uses of body materials, namely, uses of  
20 such materials for research purposes?

21

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1           The use of human biological materials for research poses a challenge to the donation  
2 paradigm, which is central to religious understandings of the body and of moral life, because it is  
3 not structured by personalized gifts of the body for therapeutic purposes. A different paradigm  
4 that seeks to bridge the gap between the donation and resource paradigms is the “offering” or  
5 “contribution” paradigm. This paradigm aims to retain the morally valuable features of the  
6 donation paradigm, while providing a justification for biomedical research undertaken without  
7 therapeutic intent. The paradigm also acknowledges the importance of medical research to  
8 generate generalizable knowledge, but works to impose some limits on the scope and extent of  
9 research on human biological materials.

10  
11           An analogy may be useful to illustrate the moral context of this paradigm. Following  
12 Belk’s suggestion that “the house is a symbolic body for the family,” in this analogy household  
13 goods take the place of human biological materials (Belk, 1990). Household goods can be  
14 discarded in several ways. One method is to donate certain goods, for example, clothing, to a  
15 community goodwill program. This presents an example of a gift or an altruistic action designed  
16 to benefit others and to enhance a recipient’s quality of life. A different set of household materials  
17 are those goods that have been used completely and are now discarded through a community  
18 service agency, for example, a trash collection service. Household refuse has no personal  
19 meaning to the discarder, who is typically quite willing to pay a fee to have the items removed.  
20 This does not, of course, pre-empt the possibility that this refuse might have value to someone  
21 else who is willing to take the time to sort through the materials. A third form of disposal consists

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1 of those household materials whose designed use has been depleted by members of the household,  
2 for example, food products that come in plastic or cardboard containers, but may subsequently  
3 undergo “recycling” by those organizations that have the knowledge and expertise to convert  
4 these materials into something beneficial for the community.

5  
6 This analogy underscores the claim that not all body organs and tissues have equal status.  
7 Some body parts, such as the heart, eyes, or blood, may have such symbolic significance and  
8 connection to personal identity that their donation is the moral equivalent of a gift of self. Other  
9 body tissues, for example, urine or cut hair, may have such minimal value to the sense of self that  
10 they are routinely discarded. Still other organs and tissues, such as a pancreas, liver, spleen, or  
11 bone marrow fall in between these examples, not as central to personal identity as the heart or  
12 eyes, but not as incidental as urine either. And, as indicated above, the status of human biological  
13 materials is shaped not only by issues of personal identity, but also of visibility and location  
14 relative to the total body. In this context, it is possible to think of human biological materials  
15 procured for research purposes as falling in this middle category and thus as analogous to  
16 domestic recyclables. The features of this analogy form the basis for the offering or contribution  
17 paradigm. The features that must be considered in this paradigm are contributor intent, beneficial  
18 expectation, symbolic re-incorporation,<sup>8</sup> and recipient responsibilities.<sup>9</sup>

---

<sup>8</sup> The religious understanding of the body that prevails in the west commonly requires some practices or rituals that re-incorporate those tissues that are removed from the body into another body, whether an organ transplant or blood transfusion into a person, or burial in the earth. The contribution paradigm can meet this condition through symbolic re-incorporation. Just as recycling contributes to the good of the communal body, the contribution of body tissues for research can provide information that can then be

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1

2           The contribution paradigm thus provides a justification for research uses of human  
3 biological materials, a justification that was absent in the donation paradigm due to its focus on  
4 direct therapeutic prospects. It also imposes limitations on research, such as the importance of  
5 the common good, re-incorporation, and informed consent, that seem absent in the resource  
6 paradigm due to its focus on using the body merely as a means to generate generalizable  
7 information.

8

## 9 **5. The Moral Obligation to Prevent Harm**

10

11           It is important to note that there is not only a societal interest in preventing harm to  
12 persons, but a moral obligation to prevent harm as well, and to determine the relevance of this  
13 moral obligation to the ethics of research use of biological samples.

14

15           According to some ethical theories, the obligation to prevent harm is not as fundamental  
16 or as demanding as the obligation not to cause harm. Such theories maintain that one is not  
17 required to bear as high a cost to prevent a harm that one does not cause as to avoid causing a  
18 harm. And there are a number of reasons to distinguish in this way between the obligation to

---

integrated within a larger, symbolic body, namely, the “body of scientific knowledge.”

<sup>9</sup> The recipient in general acknowledges contributions in some form; it thereby seems important for contributions of bodily tissue to be acknowledged with some expression of gratitude.

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1 prevent harm and the obligation not to cause harm.<sup>10</sup> Nevertheless, it would be extremely  
2 difficult to defend an ethical view that recognized a fundamental obligation not to cause harm, but  
3 failed to acknowledge even a limited obligation to prevent harm.

4  
5       Moreover, many of the reasons for asserting that the obligation to *prevent* harm is weaker  
6 than the obligation not to *cause* harm disappear or at least become less weighty when in the case  
7 of society rather than the individual. Clearly an individual cannot be required to prevent all harms  
8 to anyone who may be harmed, if only because he lacks the resources to do so. When it comes to  
9 the design of institutional schemes, however, it is possible to marshal greater resources for  
10 preventing harm, target which harms are most important to prevent, provide more effective yet  
11 still affordable harm prevention through a coordinated division of labor, and distribute fairly the  
12 costs of preventing harm. Given that this is so, whatever structures and regulations are developed  
13 for biological sample research practices should take seriously the obligation to prevent harm,  
14 understood as a societal or collective obligation. (Buchanan, 1987).

15  
16       Two obvious ways to honor the societal obligation to prevent harm have already been  
17 discussed: As a society we can attempt to develop protections for the various legitimate individual  
18 interests catalogued above, and we can facilitate the prevention of harm through the application of

---

<sup>10</sup> Perhaps most importantly, a robust obligation to prevent harm, unlike a robust obligation not to cause harm, would be excessively demanding—a conscientious effort to fulfill it would in effect make one a slave to the well being of others, including those who irresponsibly and repeatedly endanger themselves by their imprudent or self-destructive behavior.

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1 scientific knowledge in health care. The difficulty is that in some cases we can reduce the risk of  
2 harm to the individual who provides the sample only through safeguards that will impede scientific  
3 progress, and to that extent interfere with the use of scientific knowledge to prevent harms,  
4 especially those that result from disease.

5  
6         However, there is a third way in which the structure and regulation of research use of  
7 biological materials will affect the prevention of harm: restrictions on access to stored sample  
8 information may make it impossible to prevent harm to particular identifiable individuals,  
9 including the sample source. For example, suppose that in order to protect the sample source  
10 from possible insurance or employment discrimination the scientist removes all identifiers from the  
11 sample.<sup>11</sup> Later it may turn out that the individual has a particular genetic mutation, which makes  
12 him highly susceptible to a potentially lethal cancer, but one which can be successfully treated if  
13 detected early. If the sample source cannot be identified, then those who have access to the  
14 sample will know that there is someone whose life might be saved if he could be identified. An  
15 opportunity to prevent a very serious harm will have been lost, and perhaps lost in order to reduce  
16 what may be an already relatively low risk of insurance or employment discrimination.  
17 Furthermore, the opportunity to contact relatives of the sample source who are at risk for the  
18 same genetically based disease will also be lost.

---

<sup>11</sup> It is important to note that the lack of a name on a sample or on the record noting the existence of the sample does not guarantee that the sample will not be identified. A combination of demographic characteristics, plus seemingly trivial information such as the date and time at which the sample was collected may make it possible to identify the individual.

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1

## 2 **6. Interests of Researchers and Clinicians**

3

4           For many researchers and clinicians the ability to do their work effectively is of central  
5 importance to their well being and their very identity. For such individuals, practicing the most  
6 scientifically informed medicine or engaging in cutting-edge research is much more than a means  
7 of satisfying their welfare interests: it is an ulterior interest that plays a dominant role in how they  
8 live their lives. While these interests of researchers and clinicians in having access to biological  
9 samples may not be as morally weighty as are the societal interests in medical progress, they are  
10 nonetheless significant. The pursuit of these interests is not only permissible (in the sense of not  
11 being wrong), but indeed laudable, especially when compared to some goals that our society  
12 allows individuals freely to pursue. Consequently, any policy regarding the uses of biological  
13 samples that impedes the pursuit of the interests of researchers and clinicians owes them a  
14 plausible explanation of why the restrictions it imposes are needed.

15

## 16 **7. The Societal Interest in the Growth of Scientific Knowledge**

17

18           Not everyone values the growth of scientific knowledge, but most do, and more  
19 important, most if not all will benefit from it in some way or other. To that extent there is a  
20 societal interest in the growth of scientific knowledge. According to some views, the quest for  
21 knowledge is a good in itself, and is an important ingredient in human good independent of its

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1 beneficial effects. According to other views there is no societal interest in scientific knowledge as  
2 such, independently of the goods its application brings.

3  
4 Scientific knowledge makes possible improved health care, which serves several basic  
5 human interests: 1) avoiding pain and suffering; 2) restoring or preventing the loss of  
6 opportunities that depend on normal functioning; 3) avoiding unwanted death; and 4) discovering  
7 information about one's condition that can enable one to plan life more effectively, or which may  
8 simply allay worries about one's condition (President's Commission, 1983).

9  
10 The weight that should be accorded to the societal interest in benefits of applied  
11 biomedical science will depend in part upon how widely these benefits are distributed. If there are  
12 gross inequalities in the distribution of benefits, it is misleading to speak of the common interest in  
13 medical progress. Consequently, the case for tolerating greater risks to the interests of sample  
14 sources for the sake of the societal interest in medical progress is weakened if some people,  
15 including some who provide samples, lack access to important health care benefits because they  
16 cannot afford them. Nevertheless, if the benefits of medical progress accrue to a large number of  
17 people, a societal interest is relevant even if not all benefit or not all benefit equally.

18  
19 The range of medical benefits already obtained through the use of stored biological  
20 samples is impressive (see chapter 2). In many instances, access to stored biological samples  
21 collected over a long period of time has significant advantages over the exclusive use of new

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1 research protocols. Especially when the disease process under study takes place over years or  
2 even decades, studies that rely only on newly collected tissue may be very costly and produce  
3 results much less quickly than studies of stored samples.

4

## 5 **8. Commercial Interests**

6

7         It is common, and to some extent understandable, to divorce something so lofty as the  
8 interest in medical and scientific progress from economic interests, at least in political rhetoric  
9 concerning health policy. However, it is a fact, and an important fact, about all societies in which  
10 biotechnology is flourishing, that economic incentives play a central role. Biotechnology not only  
11 produces great medical benefits for individuals and for society as a whole; it also creates wealth  
12 and provides productive careers for many people who are not clinicians or researchers. These  
13 include not only those involved in the manufacture and marketing of biotechnology, but also  
14 investors in biotechnology, as well as all of us who benefit from the greater productivity of a  
15 healthier workforce. All of these economic interests also must be weighed in the balance, and for  
16 the most part they weigh in favor of less restrictive access to biological sample information.

17

## 18 **THE LIMITATIONS OF INFORMED CONSENT**

19

20         A common assumption is that some version of an informed consent requirement? perhaps  
21 a very detailed and complex one? is the appropriate instrument for protecting the various interests

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1 that could be adversely affected by the practice of collecting and storing biological samples,  
2 without excessively constraining scientific research or making it too costly to pursue (Clayton,  
3 199x).

#### 4 5 **Elements of Informed Consent**

6  
7 Informed consent is now generally recognized to be both a legal and moral requirement  
8 for medical interventions generally and for all experiments on human subjects that involve more  
9 than minimal risks. Risks are taken to include not only potential physical harms from bodily  
10 invasions, but also psychosocial harms, especially stigmatization, dignitary harms, and other  
11 assaults on the individual's sense of self-worth.

12  
13 Five elements of informed consent can be distinguished: 1) disclosure (of relevant risks  
14 and benefits of the procedure); 2) competence (on the part of the patient or subject) to make a  
15 decision whether to accept the treatment or participate in the research); 3) comprehension (of the  
16 relevant risks and benefits); 4) choice (an expressed decision to accept the treatment or participate  
17 in the experimentation); and 5) voluntariness (of the choice to accept treatment or to participate in  
18 research).

19  
20 Clearly, informed consent will play a role in any ethically sound system for collecting and  
21 using biological samples at least to this extent: the requirement of informed consent must be met

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1 for medical treatments generally and for research (involving more than minimal risk). The  
2 question is whether an ethically sound system for collecting, storing, and using biological samples  
3 will require additional or amplified applications of the requirement of informed consent in order to  
4 reduce the risks of the various harms mentioned above.

5  
6 As already noted, the requirement of informed consent developed as a safeguard against  
7 very tangible harms, the sorts of physical harms that the law generally regards as batteries (Faden  
8 and Beauchamp, 1986). In other words, informed consent first and foremost protects individuals  
9 from nonconsensual invasions of their bodies. Informed consent was not originally invoked as a  
10 general protection against all the various harms that can result, whether directly or indirectly, from  
11 medical interventions or from research. Even when understood as also providing protection  
12 against psychosocial harms, informed consent cannot reasonably be viewed as protecting the  
13 whole range of heterogeneous interests that may be affected by the uses of biological samples.

14  
15 Moreover, even if informed consent can serve to protect against the harms of deception  
16 and manipulation, that protection might be served by disclosure of the fact that the sample will be  
17 stored and later may be used for a wide range of purposes, without requiring either general or  
18 specific informed consent. Hence it is one thing to agree that freedom from nonconsensual bodily  
19 invasions and from psychosocial harms is so important that informed consent is a necessary  
20 condition for the participation of human subjects in research, quite another to say that an adequate  
21 informed consent document for biological sample practices must ensure the sample source full

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1 control over every choice that may be made in the future concerning the uses of the sample. To  
2 emphasize a point made earlier, the mere interest in having more rather than fewer choices, as  
3 distinct from the interest in significant opportunities for genuinely autonomous choice, does little  
4 to support a requirement of informed consent so far as the uses of biological samples are  
5 concerned.

6  
7 Two distinct but equally important points must be emphasized. First, the justification for  
8 informed consent focuses primarily on some, but not all possible harms, and not on the mistaken  
9 notion that informed consent enhances autonomy simply by virtue of multiplying choices.  
10 Informed consent is primarily a protection against nonconsensual bodily invasions and against  
11 dignitary harms that can generally be ranked under the category of treating persons  
12 disrespectfully, as if they were mere means for the pursuit of others' ends. It is not a device for  
13 maximizing an individual's range of choices; one would only view it in that way if one erroneously  
14 assumed that an individual's autonomy is violated whenever he is not given the widest range of  
15 choices possible.

16  
17 Second, these two types of harms against which informed consent is designed to protect  
18 are certain to occur if informed consent is not secured, because nonconsensual bodily invasions  
19 and disrespectful treatment are themselves harms, quite apart from any further harms that may  
20 occur. Yet most of the harms mentioned previously are not certain to occur and in many cases  
21 are in fact extremely unlikely to occur. It is one thing to argue that the prevention of the certain

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1 and serious harms of nonconsensual bodily invasion and disrespectful treatment justifies  
2 restrictions on research, quite another to argue that the mere possibility of various harms, some of  
3 which are not so serious and which are very unlikely to occur, provides an equally compelling  
4 reason to restrict research.

5  
6 Furthermore, it is important to stress that the primary harm against which the requirement  
7 of informed consent is supposed to protect is a serious one: if a person is not free from unwanted  
8 invasions of this body, i.e. if his body is treated as a mere object to be dealt with as others choose,  
9 neither his life nor his liberty are secure. As reasons for restrictions on scientific research, the  
10 need to prevent nonconsensual bodily invasions and the treatment of persons as mere means, on  
11 the one hand, and the “need” to protect against a range of possible, but in some cases highly  
12 improbable, harms of varying degrees of seriousness are not on a par. This is especially true in  
13 terms of possible harms that might occur after the sample has already been taken and hence after  
14 no risk of unwanted bodily invasion is at issue. Once this fundamental point is appreciated, it  
15 becomes clear that there is a large gap between identifying various potential harms that might  
16 result from a system in which individuals lose control over what is done with their biological  
17 samples and making a plausible case for introducing an elaborate system designed to extend their  
18 control, whether through some system of specific consent requirements or in some other way.

19  
20 Even if we restrict the scope of safeguards against harms (as opposed to maximizing  
21 choices), the mere possibility that a harm of significant magnitude might occur is not sufficient to

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1 warrant restricting potentially beneficial research. An appropriate threshold of risk, a level of  
2 probability of harm high enough to warrant protective measures, must be identified and defended,  
3 no easy task given the difficulty of reliably determining when that threshold has been met. Yet  
4 without exception, current proposals for specific consent requirements for various uses of stored  
5 samples assume that the threshold is defined or, even worse, the goal is to eliminate risk entirely.  
6 Such approaches simply fail to address the problem of bridging the gap between the identification  
7 of potential harms and the conclusion that special arrangements are needed to safeguard against  
8 those harms.

9  
10 It is worth dwelling for a moment on why any approach to structuring and regulating  
11 biological sample practices that assumes that the various risks identified above are to be reduced  
12 to zero is radically misguided. This assumption would only make sense if risk-reduction measures  
13 were without cost. But of course they are not; efforts to reduce risk are costly not only in terms  
14 of the resources needed to devise them and to apply them and monitor their application; they also  
15 are detrimental to the various interests that are furthered by freer access to samples.

16

## 17 **General Consent**

18

19 One measure that has been proposed to protect against the various risks that can arise  
20 from the uses of human biological materials is general or open-ended consent, either alone or with  
21 a requirement of specific consent for some particular uses of the sample or for those types of

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1 research that might be regarded as especially problematic. Thus, for example, it has been  
2 suggested that at the time a biological sample is to be taken the potential source must be told that  
3 at that time she may consent to or object to any future research uses that may be made of the  
4 sample, so long as the sample is rendered nonidentifiable with the source, with the additional  
5 requirement that specific permission is to be obtained from the source for any use of the sample in  
6 which the source's identity could be ascertained. The chief attraction of the general consent  
7 component of such an arrangement is that it requires lower administrative costs than specific  
8 consent for each future use, since one informed consent process authorizes an indefinite number  
9 of future uses.

10

11         However, the difference between general consent and what is ordinarily understood by  
12 informed consent is so great that it is problematic even to use the same term “consent” to refer to  
13 both. As noted earlier, a key element of informed consent is disclosure of the relevant risks and  
14 benefits of the procedure that is to be accepted or refused. “Relevant risks” here does not mean  
15 all possible risks. In general, what counts as a relevant risk are those that a reasonable person  
16 would want to be apprised of, though for some types of decisions a case can be made for a more  
17 “subjective” standard, a requirement that the individual must be informed of those risks that they  
18 would need to know to make a reasonable decision, given their particular values. But regardless  
19 of whether an “objective” or a “subjective” standard of relevance is employed, the rationale for  
20 informed consent presupposes the ability to identify a much more determinate and limited set of  
21 relevant risks than is generally available in the stored biological sample setting.

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1

2           Just as significant, the less determinate the set of potential harms is and the more uncertain  
3 it is that they will occur, the less likely it is that a second essential element of informed consent  
4 will be present, namely, comprehension. Moreover, once the sample has already been taken, the  
5 primary harm against which informed consent provides protection, namely, nonconsensual bodily  
6 invasion, is no longer at issue.

7

8           For these reasons, it must be acknowledged that general consent requirements are only  
9 distantly related to informed consent and do not perform the functions of informed consent. The  
10 question, then, is whether, despite this difference, general consent requirements serve any useful  
11 purpose effectively enough to warrant changing current practices to incorporate them.

12

13           It seems clear that general consent requirements will not provide protection against most  
14 of the more tangible and serious harms that might occur from the uses of stored biological  
15 samples, unless it should turn out that most potential sources refuse to give general consent. In  
16 that case, the general consent requirement would serve a protective function, but only at the cost  
17 of thwarting the various important interests that are served by scientific research.

18

19           Recall that when a person gives ordinary informed consent they thereby avoid a definite  
20 harm? the harm of nonconsensual bodily invasion? and in addition, because the relevant risks and  
21 benefits of treatment or participation have been disclosed for their consideration, they are in a

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1 better position to avoid a choice that is likely to produce other harms to them on balance. But  
2 when an individual gives general consent to future uses of their tissue, they do not thereby avoid a  
3 harm, and their choice is not likely to reflect a reasonable estimate of what is good for them on  
4 balance, simply because the information they have about possible future risks is too indeterminate.  
5 Furthermore, there is another source of indeterminacy that can undermine the requirement of  
6 comprehension: the individual may be uncertain about their own evaluation of the events that  
7 might occur in the future.

8  
9 At this point a proponent of general consent might object that protection from harms,  
10 whether physical or dignitary, is not the only point of the requirement: it also shows respect for  
11 the individual's autonomy by giving an individual control over what happens to the sample in the  
12 sense that they may refuse to allow any future uses. It may be true that a system that includes a  
13 requirement of general consent for future uses of nonidentifiable biological samples in some sense  
14 shows more respect for individuals than one that merely requires disclosure of the fact that the  
15 sample may be used for various purposes in the future. But it would be hyperbole to say that a  
16 system that does not include the requirement of general consent violates anyone's "right to  
17 autonomy." Not all choices warrant the stringent protections that talk about a right to autonomy  
18 implies; some choices are relatively insignificant because they are largely irrelevant to a person's  
19 well being and values. And, general consent may not be the only way to protect the interest in not  
20 being treated disrespectfully: simply disclosing that the sample will be stored and may be used for  
21 an indefinite number of uses in the future would go a great distance toward protecting this

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1 interest.

2

3 Finally, given the fact that general consent is only a pale shadow of informed consent and  
4 given that it does not provide significant protections from the various harms it is supposed to  
5 avert, it is far from clear that the deference to individual choice it expresses is worth the costs.  
6 Among those costs is the risk that the genuine informed consent will be devalued through  
7 confusing it with general consent.

8

9 None of this is to say that it would be impermissible to institute a requirement of general  
10 consent for future uses of samples. Rather, the point is that if such a requirement is instituted it  
11 should be recognized it for what it is: a largely symbolic expression of respect for individual  
12 choice and one way, though not the only way, of avoiding the disrespect that would be shown by  
13 a practice that keeps sources uninformed, not a case of genuine informed consent, not a  
14 vindication of the right to individual autonomy, and almost certainly not an effective protection  
15 against the various other possible harms that might result from uses of biological samples.

16

### 17 **PROPOSALS FOR “COMMUNITY CONSENT” OR “COMMUNITY CONSULTATION”**

18

19 By a community here is meant roughly a group that is more than a “mere association”—  
20 one which figures in an individual's conception of who she is, what she values, and what is  
21 valuable about her. Thus an individual may at the same time belong to a religious community, an

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1 ethnic community, a national community, and a community based on the type of career they  
2 pursue (Buchanan, 1989).

3

4 Some parties to the debate over the uses of biological samples have suggested that in  
5 some cases community consent, or at least community consultation, in addition to or instead of  
6 individual consent, may be appropriate for some or all research uses of biological samples. Three  
7 quite different rationales for this proposal must be distinguished.

8

9 The first, and more radical of the three is that at least for certain types of communities, the  
10 assumption of individual agency upon which the doctrine of informed consent is erected is  
11 inapplicable or profoundly misleading. According to this view, in some communities (in particular  
12 some indigenous peoples) individuals are so deeply embedded in the collective that to rely  
13 exclusively on individual informed consent or perhaps to require it at all is to impose an alien  
14 value scheme that assaults the very identity of the group. In its most extreme form, this first  
15 rationale amounts to the claim that the group has a right to control what happens to the bodies of  
16 its members and that individual members are not competent to decide for themselves whether to  
17 allow the collection of biological samples from their own persons.

18

19 The second, less radical rationale is that some individuals, especially those in “traditional”  
20 societies, customarily rely upon collective decision-making practices or at least upon consultation  
21 with those who occupy certain important roles in the community or who are recognized

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1 representatives of the community's values. According to the second rationale, the group does not  
2 have a right to control what is done to the individual's body, but it may be important nonetheless  
3 to enable the individual to rely upon the community, or certain representatives of the community,  
4 in making his or her decision.<sup>12</sup>

5  
6 A third rationale for community consultation is based on the interest in avoiding group-  
7 based harms. Like the second rationale, and unlike the extreme version of the first, the third  
8 rationale does not assert that the group has a right to control the individual member's body.  
9 Instead, the idea is that where there is a significant risk of group-based harms, the other members  
10 of the group have a legitimate interest in avoiding such harms since they will suffer them.

11  
12 The first rationale ought to be rejected. Showing proper respect for the value that  
13 community plays in the lives of many people, indigenous and otherwise, does not require denying  
14 that individuals are moral agents or that they have the right to control what is done to their  
15 bodies. If individuals of certain groups wish to allow others to decide for them, they can do so

---

<sup>12</sup> Although there is some ambiguity on this point, this seems to be the position of Morris W. Foster, Ann J. Eisenbraun, and Thomas H. Carter, in "Communal Discourse as a Supplement for Informed Consent for Genetic Research," xxx. While these authors do not explicitly attribute a group right to control individual members' tissues, they do talk in very misleading ways that suggest unwarranted assumptions about the cohesion or indeed the unanimity of group members as to values. Consider, for example, the following passage. "Two native American Communities we studied treated individual health care decisions as occasions for consultation within extended families. Both asserted that individual illnesses (and actions taken to care for them) can have consequences for other members of the family and community." Notice that the phrase "both [communities] asserted" is a reifying description that conveys the almost certainly false impression that there is unanimity and complete homogeneity of values within the group. In the past decade anthropologists have given up the myth that "primitive" communities are lacking in dissent and disagreement and that the values of such groups are fixed and not contested.

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1 within the framework of law and ethics that the ordinary model of informed consent provides:  
2 they can simply follow the guidance of the elders or the council, for example, or they can formally  
3 delegate decision making authority to them.

4  
5 The second rationale can provide a plausible justification for facilitating the individual's  
6 consultation with the group (or certain members of it). This may require modifying the customary  
7 ways in which researchers enlist subjects and secure informed consent. However, the second  
8 rationale does not provide a justification for requiring consent by the community or its putative  
9 representatives.

10  
11 Where the risk of group-based harm is substantial, the third rationale can justify  
12 community consultation and perhaps community participation in the design and implementation of  
13 a research protocol. Like the second rationale, it does not justify a community veto on individual  
14 participation.

15  
16 Although the second and third rationales have their attractions, it is important to note that  
17 the concept of community consultation they employ has several inherent drawbacks. First of all,  
18 there is the problem of identifying the relevant community. In the modern world, most individuals  
19 are members of a number of different, sometimes overlapping communities. Even if consulting  
20 with all the communities which contribute to the individual's identity were feasible, it cannot be  
21 assumed that the distinctive values of the various communities to which an individual belongs

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1 would yield the same conclusion when applied to the question of whether a sample may be taken,  
2 how it may be used, or who should decide. Persons' various communitarian identities are not  
3 always harmonious.

4  
5 Second, there is the problem that consultation may become coercion--that once a  
6 community (or the self-styled leader of the community) is mobilized it may exert undue pressure  
7 on the individual to conform. Given that individuals in almost all cases belong to more than one  
8 community, there seems to be only one morally defensible way of determining which community,  
9 if any, ought to be consulted: by letting the individual herself decide. No other approach is  
10 compatible with respect for the basic rights to freedom of association and religion that are  
11 essential to a liberal democratic political order. But if this is the case, then a proper consideration  
12 for "community consultation" ought to be regarded as one possible form the process of individual  
13 informed consent may take, not as an alternative to it.

14  
15 Third, it is a profound mistake to think that either a community's values or who speaks for  
16 those values can be readily identified. Especially in our multicultural world where virtually no  
17 community is impervious to a multitude of influences from without, there is no such thing as  
18 unanimity of values within a community on any issue of consequence.

19  
20 Furthermore, there are ongoing and sometimes quite subtle contests among members of  
21 the community to determine what the community's "authentic" values are and who is to be

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1 regarded as voicing them. Because until recently outsiders have wrongly assumed that “primitive”  
2 or indigenous societies are not only homogeneous in values but also unchanging, contests over  
3 what the group's values are have gone largely unnoticed.

4  
5 Just as important, it is almost never the case that what are blithely called community  
6 decisions are in fact collective decisions of all members. Instead, they are the decisions of  
7 political elitists whose interests may diverge significantly from those whom they claim to  
8 represent. To put the point most bluntly: indigenous or “non-Western” societies are frequently  
9 not only much less homogeneous but also much-less egalitarian in their decision-making than  
10 what has been called “the myth of primitive harmony” suggests (Edgerton, 1992; Lawson, xxx).

11  
12 Once these facts are appreciated, it becomes clear that the enterprise of “community  
13 consultation” is a very complicated matter, and not without risks. Whether these risks are worth  
14 taking will depend largely on three factors: 1) whether there is a significant risk of group-based  
15 harms (rather than a mere possibility of them); 2) whether other protections against the group-  
16 based harms in question are likely to be adequate, and 3) whether a process of consultation can be  
17 devised that is not likely to reinforce oppressive inequalities within the group or become an arena  
18 for political entrepreneurship by would-be leaders of the group.

19  
20 **CONCLUSIONS**

21

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1 Any ethically sound policy concerning research use of biological samples must reflect a  
2 defensible balance of the interests that weigh in favor of greater control over use and stronger  
3 protections for confidentiality and privacy, on the one hand, and those that weigh in favor of  
4 greater access to samples for purposes of research and clinical interventions, on the other hand.  
5 To frame the issue initially as a conflict between the right to privacy and confidentiality and the  
6 value of freedom of scientific inquiry is unilluminating, especially since the content and limits of  
7 rights to privacy and confidentiality cannot be determined prior to articulating and judiciously  
8 weighing all the relevant morally legitimate interests at stake.

9  
10 The major interests that weigh in favor of greater control by sources and more rigorous  
11 safeguards for confidentiality and privacy are the interests in avoiding insurance and employment  
12 discrimination, stigmatization, group harms, familial conflicts (including those of survivors of the  
13 deceased), and objectionable use on the part of the source.

14  
15 The major interests that weigh in favor of wider access to samples are: prevention of  
16 disease in the present and the future; reproductive freedoms; improved or enhanced health; pursuit  
17 of scientific knowledge; freedom of inquiry; and various commercial endeavors.

18  
19 Given that there are important and morally legitimate interests that weigh in favor of less  
20 restricted access to samples, it would be a mistake to assume that policies should be developed  
21 that reduces the risks and harms to zero. Not all of the interests that weigh in favor of more

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1 stringent restrictions on access are of equal weight, and some are of questionable importance,  
2 especially given their low probability of occurring.

3

4 In addition to the various interests that weigh in favor of less constrained access, both  
5 society and individuals have obligations to prevent harm. A policy that requires or allows all or  
6 most samples to be rendered nonidentifiable would be an unacceptable impediment to the  
7 fulfillment of obligations to prevent harm.

8

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