Chapter 3
Ethical Perspectives on the Research Use of Human Biological Materials

The retrieval and use of human biological materials for diagnostic, therapeutic, research, and educational purposes represents a further development in the scientific study of the human body as a source of important medical information, but these same developments raise a number of ethical issues for investigators, subjects, their families, and society. This chapter focuses primarily on secular ethical considerations, with a particular emphasis on how various interests can be weighed in considering access to and restrictions on the use of human biological materials in research.\(^1\) The Commission adopted this secular perspective for many reasons, one of which was that the religious perspectives of human organs and tissues has largely focused on donation for therapeutic purposes, with very little direct discussion by religious scholars of non-therapeutic research uses of human biological materials.\(^2\)

More than 282 million human biological samples are currently stored in the United States, chiefly in pathology archives, blood banks, researchers collections, and state public health department newborn screening facilities (see Chapter 2). Some materials have been stored for decades, millions more will be gathered and stored in the next year, tens of millions more in the next decade. The individuals who are the sources of the samples are identifiable in some cases, not in others. Some samples were gathered during clinical procedures (such as surgery) in which some form of informed consent was attained, some were not. Even where there was informed consent for the procedure that produced the sample, sometimes there was no consent to some or any possible future uses of the sample. In many, perhaps most cases, individuals had no idea that

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1. Parts of this chapter have been adapted from a commissioned paper prepared for NBAC by Allen Buchanan. An Ethical Framework for Biological Samples Policy. The complete paper is available in Volume II of this report.

2. It is useful, however, to consider the religious implications of research use of such materials in terms of: 1) religious attitudes to the human body and to organs, tissues, and cells removed from the body; and 2) religious discussion of modes of transfer of body parts, such as donations, offerings, sales and abandonment. To assist in its deliberations, NBAC commissioned a paper by Courtney Campbell on religious issues, Religion and Tissue Samples. This paper is
their sample was being stored, nor any knowledge that it might be used for a variety of research purposes, by a variety of investigators.

Gathering information about an individual through the taking of a medical history or by interpreting the inscriptions on an electrocardiogram may have a different and lesser significance for many individuals or for their family members than biopsying a piece of tissue or drawing blood. The reason is that many of the interests at stake for the source of the material center on the additional information that the biological sample can yield.

Moreover, it is important to recognize that some types of medical research, genetic research in particular, raises certain special concerns because analysis of samples may not only reveal information about an individual but members of their family or groups with which they share certain characteristics. In addition, any sample containing cells from any part of the body can be subjected to genetic analysis because every nucleus of every cell of the body (with the exception of red blood cells and reproductive cells) contains the complete genetic code of the person from whom the sample was taken. As noted in chapter 1, it is in part because of the completeness and seemingly limitless uses of genetic analysis—and the concerns that some possible uses evoke—that there is currently so much interest in the ethical aspects of the practice of gathering and storing human biological samples that may be used for research.

Considerations about the ethical use of human biological materials in research entails a balancing of societal interests in the benefits of applied biomedical science (e.g., improved health) on the one hand, and the avoidance of harm to the individuals who provide the material on the other. These goals are not always in opposition to each other and do not necessarily pit the interests of the future beneficiaries of current biomedical research against interests of those who have provided the human biological material. First, scientists share the moral (and often legal) obligation to design their experiments to minimize and, where possible to eliminate harm. Second, individuals often eagerly participate in research studies because of feelings of altruism or general social benevolence. Thus, virtually all parties to the discussion acknowledge both the

available in its entirety in Volume II of this report.
value of biomedical research and, the need to minimize harms such as invasion of privacy and loss of confidentiality. Nevertheless, the decision to use human biological materials in research often involves a genuine balancing of interests where the persons supplying the material are exposed to certain risks despite the potential benefit that the study may generate. Moreover the weights of the various interests vary both over time and among cases.

For example, the weight that should be accorded to the societal interest in benefits of applied biomedical science will depend in part upon how widely these benefits are distributed. If there are gross inequalities in the distribution of benefits, it is misleading to speak of the common interest in medical progress. Consequently, the case for tolerating greater risks to the interests of sample sources for the sake of the societal interest in medical progress is weakened if some people, including some who provide samples, lack access to important health care benefits because they cannot afford them. Nevertheless, if significant benefits of medical progress accrue to a large number of people or people suffering from a rare, but debilitating or lethal disease, a societal interest is relevant even if not all benefit or not all benefit equally.

NBAC focused on the possible harms that persons can suffer if others gain information from their biological samples or use those samples in various ways. In doing so, the important moral concerns that lie behind the notions of harm, such as violation of privacy and confidentiality, are brought to the fore and policies regarding appropriate protections emerge.

The Commission examined the following potential harms as worthy of consideration when using human biological materials in research.

- dignatory harm
- objectionable, unacceptable, or questionable research
- invasion of privacy
- inappropriate disclosure of confidential information
- stigmatization
- insurance and employment discrimination
- familial conflict and/or psychosocial harm
• group-based harms
• harms to survivors
• concerns about commercialization.

Obviously, the easier the linkage between source and sample and the more widely available the information is linking the source and the sample, the greater are the concerns about risks shouldered by persons providing the human biological material. It is important to note that even a significant potential harm may represent a very low risk if the probability of its occurrence is very small.

Dignatory Harms

Each person has an interest in being treated as a person, as a moral agent with unique values, preferences, commitments, and conceptions of the good. Part of the moral justification for the requirement of informed consent in research and treatment is to ensure that patients and research subjects are treated respectfully as agents, not as passive objects to be used for the ends of others.

First and foremost, however, the requirement of informed consent protects individuals from nonconsensual invasions of their bodies. Because the right of informed consent, which includes the right to refuse treatment, allows the individual to decide whether the risk of these harms is worth taking, it can also protect individuals from other tangible harms that may result from the bodily invasion, if the individual chooses not to accept the proposed treatment.

It is important to note that these harms are not restricted to the minimal harms that might occur from techniques such as drawing blood or swabbing cells from the inside of the cheek. The point, rather, is that if one allows others access to one's body for these purposes one is in a position of vulnerability to other unwanted and more dangerous intrusions. For this reason it is somewhat misleading to say that the only harm from which one is protected by informed consent and IRB review for a simple procedure such as drawing blood is the extremely remote possibility of harm from the needle stick (beyond the unpleasant momentary sensation of the pricking itself).
A strong case can be made that current practices concerning biological samples sometimes fail to treat persons with due respect because they often unintentionally mislead persons as to why samples are being taken and to what uses they will be put. It is true that the person who draws the blood sample may not know that the sample will be stored indefinitely and may be used in any number of ways in the future and hence may have no intention to mislead. Nevertheless, the institutionalized practice of storing biological samples for future uses is one for which those who control the practice are responsible, and this practice, as we have seen, often does not inform sample sources about what may happen to the sample. Given the various interests already listed above, a practice that is misleading in this way fails to show proper respect to sample sources.

**Objectionable, Unacceptable, or Questionable Research**

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

It is difficult to know how much weight this interest ought to be given in designing an ethically sound and feasible system for regulating practices concerning the uses of biological samples. First, no one knows at present the full range of possible uses for biological samples in the future; the science of molecular biology and genetic technology is evolving rapidly. Consequently, at some point in the future someone's biological sample might be used in ways that he or she finds inherently wrong. The uncertainty here is not just a function of ignorance of the technical possibilities; future cultural attitudes and regulations (e.g., concerning experiments on human subjects) could change and constrain possible uses of biological samples, independently of any control that might be exercised by the individual who is the source of the sample. Of course,
respects for autonomy may argue for giving some weight to an individual's preferences even when they are based on patently false beliefs or speculation; but nonetheless, the fact that a preference is based on patently false beliefs or speculation should surely reduce its moral weight, other things being equal. What does seem likely is that in some cases what we would now regard as wrong or at least problematic we may regard as acceptable in the future, when society attitudes have changed.

Invasion of Privacy

People have an interest in not being subjected to unnecessary exposure of the body to the view of others and in not having embarrassing or intimate facts about themselves disclosed, independent of whether such exposure or disclosure threatens other interests they may have or produces other harms. For example, one has an interest in others not knowing certain intimate information about one’s reproductive history and in not having one’s body unnecessarily exposed to view, even if these breaches of privacy cause no tangible harm.

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

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

Inappropriate Disclosures of Confidential Information

For the most part, once the biological sample is removed from the body, it is the interest in
confidentiality, rather than the interest in privacy, that is at issue. The term “confidentiality” means “with trust”; preserving the confidentiality implies keeping confidences, of confiding in those we trust. With some risk of over-simplifying, confidentiality may be thought of as a kind of second best to privacy. In some contexts, medical and otherwise, persons must expose themselves to the gaze of others or divulge sensitive information to them in order to gain certain benefits, and the best they can hope for is that there will be no unnecessary or otherwise inappropriate viewing or disclosure to others, and that those who gain this intimate knowledge of them will not use it to their detriment.

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

Stigmatization

Even if an individual is not denied insurance or employment, he or she may suffer the harm of stigmatization. Although there is an unfortunate tendency to focus only on the stigmatization that results from being identified as having a genetic disorder, other types of illness can be equally or even more stigmatizing (e.g., sexually transmitted diseases, disfiguring diseases, and cancer).

Stigmatization is closely related to discrimination; indeed it can be considered as a type of discrimination. Like discrimination, stigmatization is a form of exclusion by labeling, in which there is usually at least an intimation of unwholesomeness, blame, or taint. Some, but not all forms of discrimination include this feature.

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

As with discrimination, the weight that should be accorded to the interest in avoiding stigmatization varies among individuals and with cultural attitudes toward disease. For example, some might find it stigmatizing to learn, as the result of participating in a research study, that they possess a genetic marker that predisposes them to psoriasis, a condition that can be disfiguring. Others might not consider this to be stigmatizing. Some consider it to be stigmatizing to be a Tay-Sachs carrier because it has the potential to put the health of future children at risk; others who have been found to be such carriers do not view such information as stigmatizing (American Jewish Congress, 1998).

When, in the future, the public becomes better educated about the nature (and universal prevalence) of genetic susceptibility to disease, the risk of stigmatization on genetic grounds may diminish. And as with insurance and employment discrimination, the actual risk of stigmatization associated with various types of information contained in biological samples, as opposed to the mere possibility of stigmatization, is unknown.

 Insurance and Employment Discrimination

Given current social and institutional arrangements, persons known to have health problems or susceptibilities to disease may be vulnerable to insurance and employment discrimination. On the other hand, being listed in a tumor registry or replying truthfully to questions about one’s family medical history may be just as risky as having a positive test for a genetic disorder reported in one’s medical records.

Although some evidence has been presented (Lapham, 1996), the actual extent of insurance and employment discrimination on genetic grounds is a matter of speculation because most of the evidence comes from surveys in which individuals self report discrimination, with little or no independent check on the accuracy of their perceptions (Billings, 1992). Moreover, the risk exists only for insurance policies whose issuance is conditional on individual medical
underwriting, and most Americans who have private health insurance obtain it through employment-based, large group policies in which there is no individual medical underwriting. At the same time, some forms of individual underwriting may effect tens of millions more Americans (Stone, in Murray, 1996). Nevertheless, were insurance or employment discrimination to occur the results could be devastating for the individual.

The weight that should be accorded to the interest in avoiding insurance or employment discrimination varies with the magnitude of the risk, and hence with the institutional arrangements that either magnify or diminish that risk. For example, if blood were collected from identifiable individuals for use in a study of the basic biological mechanisms of platelet formation, one could argue that the risk of disclosure of that information poses little, if any, risk of discrimination to the individual who donates the blood. If the very same samples, however, were then later used to determine whether trace amounts of alcohol could be found in the blood, the potential for discrimination, and therefore concern, increases. And, if that blood were collected in the context of the workplace, concerns about the potential for discrimination would become even more pronounced.

The risk of insurance discrimination is not an inevitable effect of the existence of information about illness or susceptibility: it is a byproduct of the current structure of our insurance market in which most medical insurance is employment-based and in which some private insurers compete in part, by attempting to avoid fully insuring sick (and therefore costly) individuals. If this particular set of institutional arrangements were abolished or modified in certain ways so as to reduce the risk of discrimination, then the weight of the interest in avoiding discrimination would diminish. At the same time, the case for restricting access to biological sample information in order to protect the interest of avoiding insurance discrimination would diminish. (It is also important to emphasize, however, that discrimination in life insurance and disability insurance, as compared to health insurance, also occurs in other countries, which also depend on private insurance in these areas (Knoppers, 1997).

It follows that in a society like ours, in which there is a powerful institution that poses a
significant threat of discrimination on the basis of genetic or other medical information, greater
restrictions on access to biological sample information will be needed than in a society in which
these conditions are absent. If federal and state laws prohibiting insurance and employment
discrimination on the basis of genetic and other medical information are passed and effectively
implemented, the balance between interests that weigh in favor of more restricted access and
greater source control and those that weigh in favor of freer access and more permissive uses of
biological samples would shift accordingly. Therefore, whatever policy is now developed should
leave the possibility of revision in the future.

Familial Conflict and/or Psychosocial Harm

In some instances, biological sample information, like other medical information, may be a
source of intra-familial conflict. For example, genetic analysis of a blood sample may reveal that
the husband is not the father of the child. Or if a daughter tests positive for Huntington’s disease,
she reveals the genetic status of her parents, who might not want to know this devastating
information. As another example, in some cultures if a family finds out that the prospective
spouse of one of their members has a genetic disorder or a certain medical condition, they may
attempt to prevent the marriage from taking place. Regardless of whether the beliefs on which
they are based are rooted in mistaken views about genetics or indefensible assumptions about
responsibility for disease, the conflicts they can generate and the resulting harms are quite real.

In addition, finding out that one is, for example, a carrier for a genetic condition,
predisposed to heart disease, or infected with the HIV virus, can force families into difficult
situations, emotionally, physically, and economically. The knowledge that one is at elevated risk
for disease or may have unwittingly passed on a deleterious genetic trait to one’s offspring is
sensitive information that, if obtained and delivered, should be done perhaps with the full
knowledge and consent of the individual from whom the sample came.

Group-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. The harm of negative racial stereotyping, for example, 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 obtained from their biological samples contributes to the reinforcement of harmful stereotypes. Thus, limiting considerations of potential harms to those affecting the individual research subject is arbitrary from an ethical standpoint, especially given the power of new biomedical research technologies.

The potential harms that individual research subjects may suffer are harms that other members of their ascriptive group who have not contributed samples can also suffer as a consequence of the research. Research designed to study a group, or which retrospectively implicates a group, may, for example, place the group at risk of being perceived as unusually susceptible to disease. This, in turn, could result in members of the group facing, among other things, stigmatization and discrimination in insurance and employment whether or not they contributed materials to the study. What is at issue for both the individual research subject and the group is that the research might expose information about them—namely, the higher probability of the occurrence of disease—which places them at risk of psychosocial and other harms.

An individual whose identifiable sample reveals her or him to be especially susceptible to a disease may be at greater risk of harm than those individuals about whom there does not exist such specific information. This fact may sometimes justify the special protections afforded the individual research subject. However, there may be circumstances in which the individual research subject faces less risk of harm than other members of a group to which he or she belongs. For example, a socially and economically well situated research subject will likely be at less risk of suffering the effects of insurance and employment discrimination than less fortunate members
of the group. Moreover, the stigma associated with a disease may be far more injurious to a
group than to a particular individual, especially where the group is one that is already socially and
politically marginalized.

Harms to Survivors

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

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

Concerns about Commercialization

Clusters of interests concern the distribution of the financial gains that may be produced
through the uses of samples.

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

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

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

At this point it might be objected that it is misleading to talk only of the interest that individuals have in a share of the profits derived from uses of their biological samples and of whether this interest should be recognized by a legal property right: individuals have not only an

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2 Moore vs. The Regents of the University of California et al, 793 P.2d 479 (Cal. 1990).
interest, but a property right, because their tissues, blood, and DNA are their property if anything
is. And indeed some moral philosophers have assumed or argued that a person's body is her
property, in the sense of a moral property right. The model of the body as “property” stems from
a claim of self-ownership, and seeks to authorize the individual person with control over the use
and disposition of their body and of body parts (Scott, 1981; Andrews, 1986). This view tends to
treat the body as incidental rather than intrinsic to personal identity; the body as a totality is
distinct from the self, and body organs and tissues can be transferred or alienated to others
without compromising the nature of the self. These features make the property model very
conducive to the scientific interest in body tissue; with the proviso that informed consent is
obtained from the person. However, conflict can arise when, for example, a patient and a
researcher assert competing claims or “property rights” to excised body tissues, as the Moore
cases shows. It should be noted as well that there are non-instrumentalist views of the body that
are important in prominent cultural and religious traditions in the United States. The conflicting
religious and philosophical traditions that inform the discussion of the body as property make this
a topic to be more fully considered in another context. For this report it is sufficient to note that
those conflicting traditions form a background against which to consider the research use of
human biological materials.

### Protecting Interests: The Parameters of Informed Consent

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

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

Clearly, informed consent will play a role in any ethically sound system for collecting and using biological samples at least to this extent: the requirement of informed consent must be met for medical treatments generally and for most research. The question is whether an ethically sound system for collecting, storing, and using biological samples will require additional or amplified applications of the requirement of informed consent in order to reduce the risks of the various harms previously mentioned.

Two distinct but equally important points must be emphasized. First, the justification for informed consent focuses primarily on some, but not all possible harms, and not on the mistaken notion that informed consent enhances autonomy simply by virtue of multiplying choices. Informed consent is primarily a protection against nonconsensual bodily invasions and against dignatory harms that can generally be ranked under the category of treating persons disrespectfully, as if they were mere means for the pursuit of the ends of others.

Second, these two types of harms against which informed consent is designed to protect are certain to occur if informed consent is not secured, because nonconsensual bodily invasions and disrespectful treatment are themselves harms, quite apart from any further harms that may follow. Yet most of the harms mentioned previously are not certain to occur and in many cases are extremely unlikely to occur. It is one thing to argue that the prevention of the certain and serious harms of nonconsensual bodily invasion and disrespectful treatment justifies restrictions on research and quite another to argue that the mere possibility of various harms, some of which may not be so serious and others which are very unlikely to occur, provides an equally compelling reason to restrict research.

Once this fundamental point is appreciated, it becomes clear that there is a large gap between identifying various potential harms that might result from a system in which individuals lose control over what is done with their biological samples, and making a plausible case for
introducing an elaborate system designed to extend their control, whether through some system of specific consent requirements or in some other way.

CONCLUSIONS

Any ethically sound policy concerning research use of biological samples must reflect a defensible balance of the interests that weigh in favor of greater control over use and stronger protections against harms, on the one hand, and those that weigh in favor of greater access to samples for purposes of clinically beneficial research and/or clinical intervention, on the other hand. These interests vary in weight and impact depending on the extent of identifiability of the sample source and the magnitude of risks and potential benefits.

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

Given that there are important and morally legitimate interests that weigh in favor of less restricted access to samples, it would be a mistake to assume that policies should be developed that reduces the risks and harms to zero. Not all of the interests that weigh in favor of more stringent restrictions on access are of equal weight, and some are of questionable importance, especially given their low probability of occurring.

In addition to review of research with human subjects by Institutional Review Boards, informed consent has been a primary means, albeit imperfect, for protecting the interests, rights, and welfare of individuals who are subjects of research. The following chapter describes current policies and practices pertaining to the ethical use of human biological materials in research.

REFERENCES


