chapter 6

Informed Consent and Disclosure

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body."

—***Scholendorff v. Society of New York Hospital,*** ***105*** N.E. 92, 93 (1914)

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Chapter 6

Informed Consent and Disclosure

Communication is as important in research as in other professional endeavors. The communication between a physician or researcher and a patient or research subject will vary based on the situation faced by the parties involved. A physician who is removing a tumor from a patient is likely to focus on several issues that differ from those faced by a researcher who is obtaining blood samples from healthy donors for a clinical research trial. Although the dynamics of these two situations differ, an informed consent based on the communication of optimal information remains the desired result.

Consent must generally be obtained from patients and research subjects prior to specimen removal for treatment or experimentation. **Informed consent** refers to a person's agreement to allow the activity to happen, based on full disclosure of the facts needed to make a decision intelligently. Informed consent has several components: disclosure, comprehension, voluntariness, competence, and consent (11). Consent is a process, not a form. The process represents a two-way flow of information between caregiver and patient about the risks and benefits of treatment, leading to an agreement and course of action.

Once there has been a sufficient exchange of information by both parties, and assuming that the prerequisites of legal and mental capacity and voluntariness are in place, the patient is in a position to make an informed and voluntary choice. After a choice of treatment is made and the clinician agrees to carry it out, the consent process is usually complete, The practitioner may then perform the procedures that have been authorized by the patient.

Although the consent process is completed prior to undertaking medical treatment, subsequent diagnostic or therapeutic measures can call for changes in the treatment plan originally agreed to by the physician and the patient. This situation requires new disclosures of pertinent information, a continuing dialog and exchange of information, and a new or modified authorization for treatment.

Health facilities, legislation, or regulations may require a written, signed consent. Some type of written record of the consent process is often necessary to satisfy requirements regarding the quality of treatment, insurance claims, and legal defense. A consent form cannot replace the dialog between the clinician and patient; its proper role is to document that an exchange of information has taken place.

In any discussion of informed consent, it must be realized that many problems that arise can only be settled on a case-by-case basis. The parties involved often enter the consent process equipped with varying degrees of comprehension, competence, and voluntariness of action. This chapter will discuss these problems, as well as investigate the protections available to research subjects and patients,

CONSENT REQUIREMENTS FOR MEDICAL TREATMENT AND HUMAN RESEARCH

Consent requirements take many forms and are based on different principles. Professional medical societies have traditions concerning information exchange with patients. Other requirements emerge from common law, while others are based on State or Federal laws and regulations.

Common Law Consent for Medical Treatment

Common law has developed two different theories of consent. The traditional view, based on the law of battery, holds that unauthorized treat-

ment is actionable as an intentional tort (3). As such, there is no need to prove actual harm to the patient. Although the traditional view is followed in some jurisdictions, it is now well-recognized in common law that the law of battery is generally inadequate to deal with most contemporary consent issues. Patients who claim they received inadequate information about a procedure are not in a position to say that treatment was not authorized. Unless the patient can demonstrate fraud, misrepresentation, or breach of contract, there is no recourse.

The common law in some States has recognized this problem and a new theory of consent law has emerged. Based on the law of negligence, a patient can claim that the consent was invalid because the authorization was based on inadequate disclosure of information. There is no need to prove that the defendant had intentionally tried to harm or deceive the patient. Rather, based on the law of negligence the plaintiff must prove:

- the appropriate standard of disclosure;
- that a breach of that standard took place;
- that as a reasonably foreseeable consequence of this breach, the patient was harmed; and
- that had the patient been properly informed, consent to the procedure would have been withheld (24).

Important elements also include the voluntariness of consent, mental capacity, legal capability, scope of disclosure of information, and exceptions to the general rules for consent.

State Statutory Requirements for Medical Treatment

Several States have enacted so-called "consent to treatment" legislation. The impetus for many of these laws was the malpractice crisis of the 1970s. Many State legislatures also have passed malpractice reform laws, including provisions governing consent lawsuits (8) and the requirements for a valid consent (33). The negligence theory of consent has been given legislative recognition (27), and in some instances the right to bring consent actions on the theory of assault or battery has been removed,

Much of the State legislation concerning informed consent deals with setting requirements for information disclosure. These laws also contain the permissible grounds for not disclosing information to patients. Nondisclosure provisions are often found in statutes that delineate the elements necessary for a consent lawsuit or that specify valid defenses to consent actions. Medicolegal emergencies (13,15), therapeutic privilege (2,28), and requests by patients not to be informed (9,29) are examples of legislative exceptions to the requirements for a valid consent.

Federal Consent Requirements for Human Research

Following World War 11, the subject of human research generated much international, Federal, and State discussion. This produced a wide variety of pronouncements (25), guidelines (10), statutes (20)30), and regulations (45 CFR 46, 21 CFR 50) governing human research.

There are two main bodies of Federal regulations governing human research. Promulgated by the Department of Health and Human Services (DHHS) and the Food and Drug Administration (FDA), the regulations detail the elements necessary for informed consent to research and the documentation of that authorization, The DHHS regulations govern research conducted or funded by the Department, including the National Institutes of Health (NIH) (45 CFR 46). The FDA regulations govern clinical investigations that support applications for research or marketing permits for products such as drugs, food additives, biological products, and medical devices (21 CFR 50).

The DHHS regulations have been recognized as being the primary Federal requirements governing the protection of human research subjects. The Interagency Human Subjects Coordinating Committee, which has representatives of 17 Federal agencies, has proposed that the DHHS regulations serve as a model policy for all Federal departments and agencies (51 FR 20204).

As with the requirements for consent found in the traditional treatment context, the DHHS regulations make it clear that consent to research

must be obtained from the subject or his legal representative in circumstances that minimize the prospect of coercion or undue influence (45 CFR 46,1 16). The regulations specifically address issues such as confidentiality, compensation for research-related injuries, the right to withdraw from research without incurring a penalty or loss of rights, and optional disclosure requirements that can be imposed.

The regulations are quite specific in terms of consent documentation (45 CFR 46.117). In most instances, a written, signed consent is required prior to initiating research. The regulations recognize two types of consent documents, the so-called long form and the short form. The long form encompasses all the consent elements required under the Federal regulations. The short form indicates that the subject or the subject legally authorized representative has been given a verbal account of the required information. The form must be signed by the research subject or representative. The subject or representative must also be given a written summary of the oral explanation approved by the Institutional Review Board (IRB). For such a consent to be valid, the verbal disclosure must be witnessed by another person who, along with the subject or representative, must sign the short-form consent document. The person who obtains the authorization must also sign the short-form consent.

In specific situations, the DHHS regulations provide that consent requirements can be waived. Waiver can occur when the IRB determines that:

- there is no more than a minimal risk to subjects;
- the waiver will not have an adverse impact on the rights and welfare of subjects;
- *without the* waiver, it would not be practical to carry out the research; and
- under appropriate circumstances, additional details will be given to subjects following their participation in the research project (45 CFR 46.1 16(d)).

Under FDA regulations, exceptions to general consent requirements are allowed when it is not feasible to secure an authorization prior to using the test article or to preserve the life of the research subject (21 CFR 50.23), However, there is a general prohibition on using exculpatory language to release the investigator, institution, or sponsor from liability for negligence (45 CFR 46,116; 21 CFR 50.20).

Aside from its general consent regulations, DHHS has special provisions governing research using fetuses, pregnant women, and human in vitro fertilization (45 CFR 46.201-46,211); prisoners (45 CFR 46.301-46.306); and children (45 CFR 46.401-46.409).

State Consent **Requirements for *Human Research***

California, New York, and Virginia have legislated specific consent requirements for human research (5, 18)31). Each of these State laws makes it clear, however, that research subject to Federal regulatory requirements is exempt from State provisions (7)21,32), other States have less detailed legislative provisions regarding human research. These laws, frequently codified under State nursing home or long-term care statutes, are usually part of patients' rights legislation and simply indicate that informed consent is required for persons enrolled in human research (16,17). other provisions indicate that individuals may decline to participate in human research (4,23).

The fact that only a few States have enacted detailed legislation governing consent and human research, even though Federal regulations apply directly only to federally sponsored research and clinical investigations, may reflect a belief that the States are not equipped to regulate or monitor human research. It could also be interpreted to mean that State legislators do not believe the subject is so pressing as to require legislative initiatives. Another possible explanation is that Federal regulations are so detailed—and that IRBs tend to judge all research according to federally mandated standards even if not federally sponsored–that there is little need for further legal controls at the State level.

Although human research has not generated much legislative response at the State level, the laws that have been enacted convey a rather clear message regarding the well being and needs of research subjects, These State laws require a **voluntary** authorization prior to participation

from either a competent research subject or, in some instances, the subject's legal representative, with a considerable emphasis on a **written** informed consent.

Institutional Review Boards

DHHS regulations require institutions performing human subject research to create and use Institutional Review Boards to review proposed research projects for compliance with detailed human subject research regulations if the research is funded by the Department or its constituent agencies (45 CFR 46.103(b)).

Since NIH is the primary source of funding for biomedical research undertaken at medical schools, graduate science programs, and research hospitals, the regulations appear at first glance to cover human specimen research. However, research involving pathological or diagnostic specimens is exempt if the specimens are publicly available (for instance, from a tissue culture depository) or if the information is recorded by the investigator in such a manner that subjects cannot be identified (46 CFR lo).

OTA commissioned a survey of the IRBs serving 23 medical institutions to determine the practices of these institutions with respect to informed consent for specimen procurement and research. Of 22 responding institutions, none reported any special cases or problems arising with respect to using human biological materials. The survey suggests that IRBs hold researchers to more stringent ethical standards than are required by law. All of the IRBs reported that the same standards are used to review and justify all research projects in their institutions, regardless of the source of funding, even though compliance is only mandated for federally funded projects.

Voluntariness of Consent

Voluntariness of consent is an important consideration in treatment and research. For a consent to be voluntary, the authorization must be given freely. There should be no suggestion of undue influence or coercion. In reality, it is hard to insulate the patient or research subject from the most subtle—let alone sometimes overt—institutional and social pressures.

Patients may agree to treatment to avoid confrontation or to satisfy some personal, family, or social objective. Indeed, some patients suffering from serious medical problems may not be capable of a totally voluntary consent if the alternative to a proposed procedure is the prospect of lingering illness or death.

When the prospect of commercial gain is introduced into the research setting, concern arises about the voluntariness of consent. Will subjects be unduly influenced by the knowledge of possible commercial gain? Will researchers unduly influence or coerce subjects who are the source of marketable, biological material? If these are genuine concerns, what steps can be taken to minimize the prospect of a less than voluntary consent?

Factors Influencing Voluntariness of Consent

A variety of factors can influence the voluntariness of consent to participate in research. Three of these are:

- ***satisfying*** psychological, emotional, or medical needs;
- desire to please others; and
- the prospect of financial gain.

There is no doubt that for many subjects, participation in human research satisfies some psychological, emotional, or medical need. The psychological or emotional impetus for taking part in a study may not be clearly defined, but affliction with or recovery from a serious illness, or the loss of a loved one, are sometimes rationales for research participation. Taking part in a study sometimes satisfies a need for attention, In most instances, it is not troublesome that a subject participates in a research project to satisfy an emotional or psychological need. However, when researchers who are aware of this inner need exploit it to gain consent, then voluntariness becomes an issue. Controlling this problem can be difficult, particularly because the undue influence may be quite subtle yet very effective. IRBs and researchers alike must be diligent to safeguard against this problem.

The desire to please others can also pressure people into participating in research. This is par-

ticularly of concern among those persons who see their participation as a way to gain the favor of someone in authority or for whom they have considerable respect. Considerable doubt can be cast on the ability of subjects in a dependent relationship to achieve a voluntary consent. Prisoners and those in long-term care facilities typify such potential subjects. Such concerns are embodied in the DHHS regulations dealing with prisoners as research subjects (45 CFR 46.301-46.306). However, this problem can also manifest itself in other dependent groups (e.g., children, the elderly).

The prospect of financial gain may also influence a subject's decision to give consent. If a researcher places considerable emphasis on the prospect for financial gain with impoverished research subjects, such information may be an undue influence. Even compensation for expenses and inconvenience could provide some impetus to participate. The question remains whether these influences are inherently bad, or if not, are so strong as to be unwelcome. If so, safeguards could be designed to minimize their effect.

Legal Dynamics of the Physician/Researcher and Patient/Research Subject Relationship

Like the relationship between a physician and a patient, the physician/researcher liaison with a patient/research subject is one of a fiduciary trust. The physician/researcher owes a special duty of care to patient/research subjects and must not act in a way that jeopardizes the rights and welfare of participants. This includes obtaining authorizations for participation in research in a manner that is free of undue influence and based on a fair and comprehensive disclosure of information.

The danger of undue influence is as real in the research setting as it is in the medical treatment context. The results can be far worse in the treatment context, however, where subjects who agree to unnecessary procedures or tests must pay health facilities or clinicians. Moreover, in the treatment setting the institutional and IRB safeguards for human subjects are often not present.

For some physician/researchers, the prospect of **commercial gain** can represent a conflict of interest. Two distinct duties are present: one as a principal investigator and the other as an attending physician to the patient/research subject. The interests of the researcher maybe far different from the concerns of the attending physician. The researcher may see the subject as an invaluable source of scientific knowledge or perhaps commercial gain. The physician sees a patient requiring careful diagnostic testing and treatment. When the researcher and attending physician are the same person, the desire for financial gain could overshadow the concern for the well-being of the patient/research subject. Research might be carried out that would ordinarily be avoided and treatment that would usually be conducted might not be pursued.

Commercial gain is not the only motivation for unduly influencing physician/researchers. For some, the potential for **public or scientific recognition** may be more of an impetus to unduly influence subjects than the thought of reaping financial reward. While it may be difficult to discern public or peer recognition as a cause for concern, the potential exists for the physician/researcher to conduct himself/herself in a manner that unduly influences the subject.

It is difficult to determine whether or not undue influence is a serious problem in medical-based human research. If it is, there are limits to what can be done to eliminate it. Educating physician/researchers about the proper means of obtaining consent, monitoring the consent process, requiring consent documentation, and taking appropriate action when discovering instances of undue influence are all practical options. In addition, professional boards can discipline those who have acted improperly.

The ability of research subjects to perceive undue influence should not be discounted. The effect of the consumer movement has spread to health care and patients have become more reluctant to agree to treatment without first being satisfied of the need for and the costs of it. Patient-research subjects, too, are likely to inquire about the purpose, needs, and benefits of studies.

Finally, when enforced properly, the current Federal human research regulations provide a considerable degree of protection against undue in-

fluence in the consent process. Full enforcement of current provisions along with proper disclosure of the prospect for commercial gain may therefore be the most practical safeguards against undue influence with respect to human tissues and cells of potential commercial value.

DISCLOSURE REQUIREMENTS

For a consent to be valid, the patient or research subject must be given an adequate amount of information with which to reach a reasoned choice, Perhaps no other aspect of consent has generated more case law and discussion among scholars than the extent of required disclosure of information.

Disclosure requirements can vary in different settings. The following sections consider standards of disclosure in three contexts: disclosure in the medical treatment setting, disclosure in the research setting, and disclosure when potential commercialization of a product is contemplated.

Disclosure Requirements in *Medical Treatment*

In the United States, there are two schools of thought regarding the disclosure standard in consent to treatment. The traditional view, held by a majority of States, requires disclosure of information that the medical community customarily discloses to patients (24). This standard is based on what physicians view as important, as well as what facts physicians believe patients should know before agreeing to treatment.

A modern trend, adopted by a minority of States, bases disclosure requirements on what a reasonable person in the patient's position would want to know in the same or similar circumstances. Unlike the physician-oriented approach, this standard is based on patient need and recognizes that patients want to take a more active role in their treatment. To this end, patients need information that is material or significant to their decisions regarding recommended care (24).

The patient-need approach involves the patient in making decisions and it compels physicians to communicate with patients. It enlarges the consent process to take into account matters beyond the mechanics of a proposed form of care. The patient-need standard considers the probable impact treatment will have on employment and lifestyle as well as the financial and emotional costs to the patient. State courts are increasingly adopting this view in preference to the physician-based standard.

Both approaches to disclosure would generally include the following information in disclosure to patients:

- the nature and purpose of a diagnostic, medical, or surgical intervention;
- probable, foreseeable risks and benefits associated with the intervention;
- the availability of reasonable, alternative procedures and the probable, foreseeable risks and benefits associated with these optional interventions;
- an explanation of probable complications, discomfort, disability, or disfigurement associated with recommended, as well as optional, interventions; and
- the probable, foreseeable risk(s) associated with foregoing all interventions (24).

Additional disclosure requirements are sometimes needed. For example, it maybe argued that patients in teaching hospitals should be informed that students, interns, or residents may take an active role in their health care because this information may be an important consideration for some patients in agreeing to or refusing recommended therapy.

Case law recognizes that certain types of information need not be disclosed. For example, under the patient-oriented standard the clinician need not divulge information regarding:

- *risks* already known to the patient,
- obvious risks which the patient may be presumed to know,
- remote risks with a very low incidence asso-

Box D.—Physicians' and Patients' Views of Informed Consent and Disclosure

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research was established by Congress to investigate the ethical and legal implications of the requirements of informed consent to undergo medical procedures. In 1982, the now defunct Commission determined that insufficient data existed concerning physician and public attitudes toward informed consent and commissioned a national survey to investigate the issue of informed consent in therapeutic settings. Interviews were completed with a national sample of 805 physicians and a national cross section of 1,251 adults.[1]

The vast majority of physicians reported that they "always" or "usually" discuss most aspects of condition and treatment with their patients. As might be expected, the proportion of doctors who report disclosing information to their patients is greater than the proportion of the public who report that doctors discuss these matters with them. In most instances, there was a difference of 15 to 25 percentage points between the proportion of doctors who report usually discussing the issue with their patients and the number of patients who report that their doctors usually discuss these matters with them.

Seventy-three percent of the doctors and 44 percent of the patients felt the requirements of informed consent put too much emphasis on disclosure of remote risks.

Physicians demonstrated some confusion about the legal requirements related to informed consent. Only 32 percent of the physicians felt that the legal [illegible] no consent at all.

[illegible]

SOURCE: Office of Technology Assessment, 1987.

ciated with proposed care or testing, and
- risks either unknown to the clinician at the time consent is obtained or that in exercise of reasonable care could not be ascertained (26).

Case law involving the physician-oriented standard does not provide a hard and fast rule for what the doctor need not disclose. This is a matter based principally on the facts and circumstances of each case, taking into account customary practice in the medical community. Should litigation ensue in a case controlled by the physician-oriented viewpoint, expert testimony would likely be required to establish what is the acceptable scope of nondisclosure (24).

Both standards recognize certain exceptions when the need for disclosure is outweighed by other considerations (26). These include medical emergencies, situations where disclosure could be detrimental to the patient's well-being, and instances of legal or mental incapacity. Thus, disclosure of information cannot be considered in a vacuum. Whether clinicians follow either the professional or patient-need standard of disclosure, it is imperative for them to take into account the surrounding facts and circumstances of each case. How this information is interpreted and applied helps to differentiate the two standards for disclosure.

Several State legislatures have set requirements regarding what information needs to be disclosed (2,22,28,33), the types of information that need not be revealed (29,33), and the circumstances in which disclosure need not be made (13,25,33), Remote risks (2) or risks that are commonly known (2,18,29) **need not** be revealed. Similarly, medicolegal emergencies (13,15,33) and statutory versions of therapeutic privilege (2,9,28) create exemptions from the standard requirement for disclosure of information.

The law is far from settled in the area of disclosure standards and some decisions have sparked controversy. For example, how far must a physician go in making certain that a patient's **refusal** of care is informed (12)? Moreover, does the duty to reveal information about reasonable alternative procedures include mention of those procedures that are more hazardous than the recommended intervention? The Supreme Court of

Connecticut has suggested that '(reasonable" alternatives does include description or inclusion of more risky options (14). It remains to be seen whether other courts will adopt that court's definition of a reasonable alternative.

What constitutes an appropriate amount of information disclosed to a patient under the physician-oriented standard may be as hard to discern as "material" or "significant" information under the patient-oriented approach. The courts have evaded setting precise requirements. As a result, more, rather than less, case-law development can be anticipated in this area of consent.

Disclosure in the Research Setting

Federal law requires far more information to be disclosed to obtain valid consent in a research setting than in a therapeutic setting. Under Federal regulations (45 CFR 46.116) and some State statutes (6), all reasonably foreseeable risks and discomforts that subjects might experience must be disclosed,

Risk information is not the only type of information that requires greater elaboration in the research setting. Federal law also mandates disclosure regarding:

- the nature and purpose of the research;
- anticipated length of subject's participation in the study;
- procedures to be followed;
- identification of experimental procedures;
- benefits to the subject or others that maybe reasonably anticipated from the study;
- alternative procedures or treatments that may be advantageous to the subject;
- steps to be taken, if any, to maintain confidentiality of records identifying participants;
- whether compensation and treatment are available for injury arising in a study where more than minimal risk is involved;
- if compensation or/for treatment is available, what it consists of, or where additional details may be obtained; and
- who should be contacted if subjects have questions regarding the research or their rights, and the contact person in the event of research-related injury (45 CFR 46.1 16(a)).

In addition, the researcher must explain that subjects are voluntarily taking part in research and that their refusal to participate will not incur a penalty or loss of benefits to which they are otherwise entitled. Moreover, they must be told that they may withdraw from the study at any time without incurring a penalty or loss of benefits to which they are entitled.

The same States that have detailed statutes on consent and human research have similar disclosure requirements (6)19). However, the Federal regulations are more comprehensive, listing additional information that should be revealed to research subjects if deemed appropriate (45 CFR I16(b)). This may include:

- situations in which the subject's role in the study may be ended by the researcher without regard to the participant's consent,
- other costs to the subject that may result from the research study,
- the consequences of the participant withdrawing from the project and the means for an orderly conclusion to the subject's involvement,
- a statement that significant new findings achieved in the course of the research relating to the subject's willingness to carry on in the study will be provided to the subject, and
- the approximate number of persons taking part in the study.

Although Federal regulations emphasize full and candid disclosure of information, there are circumstances where an IRB may approve practices that alter or exclude some or all of the elements for consent. To do so, the IRB must document that the research involves no more than "minimal risk" to subjects, defined in the regulations as:

> [T]he risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(@).

In addition, the IRB must determine and document that modifying the consent requirements will not have an adverse impact on the rights and welfare of subjects. It must also be shown that

SAMPLE CONSENT FORM

I.R.B. NO: _____

*This form is for use when the **research will involve therapeutic procedures.***

Consent to Participate in Research

1. Project Name:
2. Project Director: Telephone:

This research was approved by the Institutional Review Board.

3. The purpose of this research is:
4. The general plan of the research is:
5. The following procedures will be performed on those who participate in this research:
6. Those who participate in this research will be asked to do the following things:
7. In order to do the research it will be necessary to change from usual therapy by:
8. This research may result in the following discomforts:
9. Participation in this research may involve the following risks:
10. Participation in this research may benefit the participant by:
11. As an alternative to participation in this study, the following treatment will be offered:
12. The investigators will do everything possible to prevent or reduce discomfort and risk, but it is not possible to predict everything that might occur. If a participant has unexpected discomfort or thinks something unusual or unexpected is occuring he/she should contact:

In the event of any injury resulting from any research procedure, acute medical care will be provided at the usual charge, but no Federal or District of Columbia Government funds will be available for compensation. Additional information on this subject may be obtained from the Office of the Medical Director.

Anyone who agrees to participate in this research may change his/her mind at any time. Refusal to participate or to continue to participate will not harm an individual's relationship with his/her physicians, the hospital or those doing the research. They will do the best they can for the individual whether or not he/she participates in this research.

I have read the above description of a research project (or it was read to me by:)* and I had all of my questions answered to my satisfaction. I agree to participate in this research. Anything I did not understanding was explained to me by:

I acknowledge I have received a personal copy of this signed consent form.

(signed) _____ _____
(Participant or Legal Representative) Data

(signed) _____ _____
(Witness) Date

(signed) _____ _____
(Investigator) Date

Rev. 6/79

SOURCE: Office of Technology Assessment, 1987.

as a practical matter the study could not be pursued without the consent modification. When appropriate, however, subjects taking part in studies in which consent requirements have been modified must be given relevant information following their participation (45 CFR 46.116(d)).

The need for a detailed disclosure of risk information in the research setting is also found in case law. As a Federal appellate court wrote:

> . . . [F]or a physician to avoid liability by engaging in drastic or experimental treatment, which exceeds the bounds of established medical standards, his patient must always be ***fully informed*** of the experimental nature of the treatment and of the foreseeable consequences of the treatment (l).

The common-law approach to disclosure in the research setting is pragmatic. The degree of information revealed to a subject will vary from case to case, but some basic principles apply. The greater the probability of risks and the more novel or experimental the procedure, the more detailed should be the information divulged to research subjects. This is an extension of the basic concepts of consent dealing with personal autonomy and the need for sufficient information to reach a reasoned decision about care.

Disclosure Requirements and Commercial Gain

In medical settings, the information disclosed to patients traditionally has focused on the risks and benefits of diagnostic tests or treatment, as well as alternative procedures. In the research context, the disclosure of information has centered on the nature of the study, the involvement of subjects, and any risks involved. However, arguments over the nature of disclosure arise when the prospect of commercial gain becomes an issue.

Arguments Favoring Disclosure Regarding Commercial Gain

Several arguments could be proposed to justify why disclosure of potential commercial gain should be required in the research setting. If the right to decide what will be done to one's own body is to be given full legal recognition, then the prospect of any person achieving commercial gain as the result of any invasive procedure should be disclosed because this information may help a person decide whether or not to take part in the research. While this information may not be pertinent to medical risks and benefits, it can be viewed as a logical extension of the information already required for consent.

Under current Federal regulations it can also be argued that at some point in the course of research, disclosure of potential commercial gain is required. The regulations require disclosure "when appropriate . . . significant new findings [are] developed during the course of the research which may relate to the subject's willingness to continue participation" (45 CFR 46.116(b)(5)). It can be argued that the discovery in a subject's body of a unique cell line that may be commercially valuable constitutes a significant new finding. This type of information could influence a subject in deciding whether or not to continue his role in the research project. As such, under the regulations it maybe the type of additional information that can be required when deemed appropriate by an IRB.

It also can be argued that in a medical treatment context, disclosure of commercial gain should be deemed "material" or "significant" information. Under the patient-need approach to disclosure, this would require that the patient be provided with such information. Since greater disclosure is usually required in a research setting, it would follow that disclosure of potential commercial gain would be required there as well.

Arguments Against Disclosure Regarding Commercial Gain

Arguments can also be made against disclosing the prospect of commercial gain. One argument opposing disclosure, is that the prospect of commercial gain is highly speculative and to bring up the subject in a consent dialog may detract from the more important aspects of the process. This interference may not rise to the level of undue influence, but it could impede subjects from taking an effective role in the consent process.

It can be argued that commercial gain should not be disclosed if it would hamper the subject's

SAMPLE CONSENT FORM I.R.B. NO: _____

*This form is for use when the **research will involve non-therapeutic procedures.***

Consent to Participate in Research

1. Project Name:
2. Project Director: Telephone:

This research was approved by the Institutional Review Board.

3. The purpose of this research is:
4. The general plan of the research is:
5. The following procedures will be performed on those who participate in this research:
6. Those who participate in this research will be asked to do the following things:
7. This research may result in the following discomforts:
8. Participation in this research may involve the following risks:
9. The investigators will do everything possible to prevent or reduce discomfort and risk, but it is not possible to predict everything that might occur. If a participant has unexpected discomfort or thinks something unusual or unexpected is occuring he/she should contact:

In the event of any injury resulting from any research procedure, acute medical care will be provided at the usual charge, but no Federal or District of Columbia Government funds will be available for compensation. Additional information on this subject may be obtained from the Office of the Medical Director.

Anyone who agrees to participate in this research may change his/her mind at any time. Refusal to participate or to continue to participate will not harm an individual's relationship with his/her physicians, the hospital or those doing the research. They will do the best they can for the individual whether or not he/she participates in this research.

I have read the above description of a research project (or: it was read to me by:). Anything I did not understanding was explained to me by: and I had all of my questions answered to my satisfaction. I agree to participate in this research.

I acknowledge I have received a personal copy of this signed consent form.

(signed) _____ _____
(Participant or Legal Representative) Date

(signed) _____ _____
(Witness) Date

(signed) _____ _____
(Investigator) Date

Rev. 6/79

SOURCE: Office of Technology Assessment, 1987.

ability to reach an informed choice free of undue influence. The prospect of financial security stemming from marketable products derived from human tissues and cells could interfere with some people's ability to reach an informed decision,

Disclosing information regarding commercial gain could jeopardize the health and safety of some subjects, as well as the validity of the research itself. For example, upon learning of the prospect of commercial gain, some potential subjects might be hesitant to relate medical or personal history information that would otherwise disqualify them from the study. This could result in studies generating invalid or skewed data. It could also jeopardize the health and safety of subjects who by their actions expose themselves to unacceptable and unanticipated risks.

Requiring researchers to disclose information about potential commercial gain is arguably inconsistent with their professional responsibility to inform subjects about health-related details. Researchers may not be sufficiently informed themselves to realistically explain the prospect of commercial gain. In fact, the researcher may not even be the physician of record who interacts with the subject. While an investigator may think there is an opportunity to successfully market unique human biological materials or products invented from specimens, in fact there maybe little likelihood of this becoming a reality. For researchers to divulge such information could convince subjects to participate in research on the basis of misinformation, unreasonable expectation, or for the sole purpose of financial gain. This would be contrary to the general principles of consent and disclosure.

Finally, full information regarding potential commercial gain may be impossible to convey in many instances since the prospect of such gain is likely to be vague and speculative at the time the sample is obtained.

Standard for Disclosing Commercial Gain

In the medical treatment setting, it is unlikely that a court following the viewpoint of disclosure held by most States would require clinicians to inform patients of the prospect of commercial gain accruing from the use of patients' tissues and cells. Based on a professional disclosure standard, the majority viewpoint is concerned with what the medical community considers necessary information for patients to know in making a treatment decision. Even with the viewpoint held by a minority of States, based on patient need, it is uncertain whether the prospect of commercial gain would be "material" or "significant" to a patient contemplating actual treatment or an invasive diagnostic procedure. It will be up to the courts or State legislatures to decide whether the possibility of commercial gain for any interested party requires disclosure where diagnostic tests or active treatment is contemplated.

In the research setting, where subjects maybe enrolled in studies offering little likelihood of direct benefit and where there may be serious known or unknown risks, disclosure of commercial gain may bean important consideration. Such information is likely to be particularly important when the marketing of a product containing human tissues and cells is quite probable. It is a factor that goes to the core of personal autonomy and a subject's determination whether or not to be the source of a commercially viable commodity. It should not be assumed that all persons, upon learning that they carry a unique cell strain or other type of biological material, will agree to its commercial marketing as a developed cell line. Some people may be opposed to such use (see ch. 8).

Safeguards can be developed and put in place that minimize any detrimental impact flowing from disclosure of probable commercial gain, if policymakers, IRBs, or researchers determine that such disclosure is desirable. These include determinations regarding the content and timing of such disclosure and the standard for revealing such information. The standard determines how much information regarding the treatment or research project will be given to the subject,

When the focus shifts to novel or experimental interventions or research, the standard for disclosure is broadened even further. No longer is the standard tied to conventional medical beliefs or the informational needs of a reasonable person. Federal regulations require disclosure of any procedures deemed experimental (45 CFR 46.116(a)(l))

and any foreseeable risks or discomforts stemming from the study (45 CFR 46.116(a)(2)).

The full disclosure requirements found in the research setting may be appropriate for most nontherapeutic or experimental studies. However, when a study focuses on human biological material it may well be asked whether the prospect of commercial gain needs to be disclosed in all nontherapeutic or research settings or if a less stringent standard would suffice?

Questions like these arise because in many instances tissues and cells can be obtained with a minimum of risk to research subjects. In other instances, diseased tissues or cells must be removed from a patient in order to save life or protect health. From a practical point of view, it may be unwise and unnecessary to impose upon all human research projects an additional disclosure requirement regarding possible commercial gain.

This view is reinforced by current Federal regulations. Research involving the collection and study of pathological or diagnostic specimens is specifically exempt from the disclosure regulations if:

> . . . these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects (45 CFR 46.101@)(5)).

Another Federal provision relates to the authority of IRBs to approve studies in which all of the elements of informed consent are not present (45 CFR 46.l16(d)). This may occur when, among other things, studies involve no more than minimal risk and such modifications will not have an adverse impact on the rights or welfare of subjects.

If research involves no more than minimal risk to the patient, and commercial gain is not likely, a blanket requirement to inform subjects about commercial gain may be unnecessary. In such circumstances, the IRB could be empowered to exclude reference to commercial gain.

However, if it is probable that research may yield a commercially significant product derived from a human sample, disclosure may become more necessary. In this instance, the pecuniary and privacy rights of subjects may be compromised if the possibility of commercial gain is not disclosed. Moreover, the welfare of such subjects might be given inadequate attention if the prospect of commercial gain clouds objectivity. When commercial gain is probable, the rights and welfare of subjects may require full disclosure.

The opportunity to identify potentially marketable tissues and cells in research may set a new but limited disclosure standard. Rather than requiring disclosure about commercial gain in all cases, it could be limited to those instances where marketable material is reasonably foreseeable. However, when information is available that is "material" to a subject's decision as well as his rights and welfare, disclosure is imperative. That a subject may garner financial security, experience a loss of privacy, or become the target for commercial ventures as a result of biological substances derived from tissues or cells is arguably "material" or "significant" information. As such, careful consideration should be given to incorporating such a "materiality" disclosure requirement in the human research regulations.

Content of Disclosure Regarding Commercial Gain

The need for a full and frank disclosure of the prospect of commercial gain must be balanced against the potential impact such a revelation may have on the ability of potential subjects to reach reasoned judgments about participating in a study. The content of such a disclosure should be consistent with other information requirements for consent (45 CFR 46.116). This would include:

- the nature and purpose of using human biological material obtained in the course of the research;
- the probable risks associated with obtaining the material;
- the probable benefits flowing from obtaining the material and the probable beneficiaries of these substances or knowledge derived from same;
- the possible commercial gain that may result from developing the biological material in question;
- a description of the method(s) the investigator intends to use to obtain the biological material from research subjects;

- the availability of reasonable, alternative ways of obtaining such material and the probable risks and benefits associated with these alternatives;
- the name and location of persons to be contacted if subjects have any questions or concerns during the course of the study;
- the availability of treatment or compensation for injuries stemming from the study; and
- the right of subjects to withdraw from or to participate in the project without prejudicing their ability to secure treatment to which they are otherwise entitled.

Timing of Disclosure Regarding Commercial Gain

Choosing the correct time to tell a subject or patient of potential commercial gain presents two different concerns. One is that the prospect of commercial gain could unduly influence the subject. The other is whether a researcher has a responsibility to inform subjects whenever new developments alter the original terms on which the consent was based.

On disclosure of possible commercial gain, some subjects may withhold information they believe might make them ineligible as participants. This could result in flawed research results and possibly put the subject and others in the study at serious and unnecessary risk. To overcome this difficulty, potential subjects must be carefully screened to make certain that they meet eligibility criteria. Only then should a full disclosure take place, including the reasonably foreseeable prospect of securing commercial gain.

A second concern relates to the probability of commercial gain discovered subsequent to the participant's entry into the study. The need for full disclosure continues until the conclusion of treatment or research. Indeed, the duty to advise patients or subjects may extend much longer, particularly when individuals are at risk as a result of treatment or research procedures. When significant discoveries are made in the course of research and they alter the basis of the consent, the investigator should reveal this information to subjects. The reasonably foreseeable prospect of commercial gain determined in the course of a research study amounts to a "significant new finding" that may have an impact on the subject willingness to carry out his role in the project (45 CFR 46.l16(b)(5)).

ARE CHANGES NEEDED IN THE CONSENT PROCESS?

The current DHHS regulations contain two provisions that concern research involving human biological material. The first excludes certain types of specimens from the regulatory requirements (45 CFR 46.101(b)(5)) . The second prohibits the use of exculpatory language through which the subject is made to waive or appear to waive any legal right (45 CFR 46.116).

Federal Research Exclusions

The DHHS informed-consent policy applies to virtually all human research funded by the Department. However, an exemption exists for research involving the collection or study of existing data, documents, or pathological or diagnostic specimens if these are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified. Researchers are therefore not obliged to disclose their research or commercial interests to providers of specimens in these instances.

This may pose an ethical problem for some people because researchers might garner commercial reward from work carried out on unknown subjects. From this point of view, it could be argued that the regulations should be amended, either by:

1. prohibiting researchers from reaping financial rewards from such discoveries,
2. requiring the application of informed consent requirements to the collection and use of such specimen material, or
3. disclosing to the subject that a specimen might be used in research that mayor may not result in the development of a commercial product.

From a practical point of view, trying to identify the human sources of "existing" specimens would be cumbersome, if not impossible. In addition, more harm than good may be achieved in trying to secure consent because research efforts can be impeded by trying to overprotect patients whose primary interest-diagnosis or treatment—is unrelated to the research.

If the consent process is changed to include a disclosure requirement concerning commercial gain, this disclosure could be limited to those instances where there is a significant probability of commercial gain (i.e., a high probability or certainty of a marketable biological material being extracted) arising from the use of human tissues and cells from an identified research subject. This information would be conveyed during the consent process, when the researcher provided other required details relating to risks, benefits, and alternate treatment options. To overcome the potential for unduly influencing research subjects, researchers should be cautious not to give any more or less emphasis to details regarding commercial gain than is given to other required information.

As with other types of information, disclosures regarding potential commercial gain should be in understandable terminology, with research subjects receiving a full and understandable explanation regarding the human tissues and cells that may be developed by a researcher into a marketable resource, as well as the definition of '(commercial gain. " Subjects should be given ample opportunity to ask questions and should be given sufficient time to carefully consider whether they want to participate in a study that might result in commercial gain.

While the law of consent is designed to safeguard the rights of the person relating to his or her body, it has its limits. Consent cannot, and arguably should not, prevent researchers from reaping financial reward as the result of research developing tissues and cells collected from another person. It can only assure subjects of a fair level of communication regarding their participation in research. The propriety of researchers achieving financial success from manipulating human specimens in their research is an issue best handled under other legal theories and principles. This may include provisions in research contracts, property law, or perhaps professional disciplinary laws.

Federal Exculpatory Language

The purpose of the DHHS human research regulations is to safeguard the rights and welfare of research subjects. This is particularly apparent in the consent regulations. This approach includes a provision which in part bans the use of exculpatory terms "through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights (45 CFR 46.116).

The intent of this provision is to safeguard subjects and to make certain that they do not wittingly or unwittingly relinquish any legal rights. This concept reinforces the notion of consent as a communication process arising from the physician-patient or researcher/subject relationship. It also reflects the concept of consent as a contractual matter in which parties on both sides should be working from positions of comparable strength. The issue arises, however, as to whether the ban on exculpatory language should be lifted for instances of potential commercial gain.

Some subjects may not want to reap financial benefits as a result of or as a byproduct of their participation in research. This may offend their sense of values and deter them from taking part in studies. Moreover, the prospect of sharing possible financial gain with a subject may have a deterrent effect on important research. Although it is true that a human being may be the source of a marketable cell line, it is the researcher who has identified and fostered the discovery. Researchers may well question the utility of conducting such studies, particularly if research subjects demand a significant share of the financial gain.

A possible change in the DHHS informed consent regulations could be made to modify the prohibition on the use of exculpatory language to permit research subjects to waive any rights to commercial gain stemming from research findings. This provision should be clearly worded, and the waiver of such rights must be free of undue influence and coercion. Research subjects should

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understand exactly what rights are being waived. They should also understand that should they decide not to waive their rights to commercial gain, they will not be denied treatment to which they are otherwise entitled. In appropriate cases, research subjects should be informed that their decision not to waive their rights to commercial gain may disqualify them as participants. When such situations arise, subjects should be told why a nonwaiver is a basis for exclusion from a study and what compensation is available to the subject who agrees to a waiver. This may take the form of an offer of a lump sum of funds to compensate the subject for waiving rights to marketable, human research material.

Permitting the use of enforceable, exculpatory language regarding commercial gain could actually enhance the rights and welfare of subjects. It is possible that researchers and sponsors may be far more protective of the source of their human tissues and cells if they need not share financial gain with subjects.

Giving subjects the opportunity to waive their right to financial gain from marketing products derived from their biological material does not obviate the need for informed consent. Indeed, with certain safeguards in place, there should be no hesitancy in permitting exculpatory language through which an "informed" subject waives legal right to possible legal rights to financial gain.

Latent Discovery of Commercial Gain

If the prospect of financial gain does not become apparent until subjects have become deeply involved in the project, generally accepted principles of human research hold that the researcher has a duty to disclose this information as soon as possible. It represents a logical perpetuation of the consent process, particularly when a latent discovery may have a dramatic impact on the original terms of consent.

Support for this view can be found in the current regulation (45 CFR 46.116(5)) that authorizes an IRB to require additional disclosures regarding "significant new findings" that may affect a subject's willingness to continue in research. An

additional disclosure with respect to the effect of withdrawal from a study could be made based on 45 CFR 46.116(4).

Role of the Institutional Review Board

If additional disclosure requirements and the use of exculpatory clauses are added to the consent process, IRBs will have a greater role. Current regulations indicate that when potential subjects are vulnerable to undue influence or coercion, the IRB should make certain that there are safeguards to protect their rights and welfare (45 CFR 46.11 l(b)). This role becomes particularly important when potential commercial gain is involved. It is equally important when researchers intend to use exculpatory language and seek waivers from subjects to commercial gain.

What could be included in these added safeguards? The following are examples of additional protections that could enhance the rights and welfare of subjects:

- careful review by the IRB of information to be disseminated to subjects to make certain that it details in comprehensive terms what constitutes "commercial gain";
- monitoring the consent process on a random basis to make certain that subjects are receiving approved information and that there is no evidence of undue influence or coercion;
- in the case of subjects who may be vulnerable to undue influence or coercion, the IRB could require the appointment of an advocate whose duties would be similar to those for children who are wards under 45 CFR 46.409(b); and
- followup procedures, such as random outcome screening to compare the experience of subjects at the conclusion of the study with research protocols, information sheets, and consent documentation presented to participants at the outset of the project.

Should researchers determine in the course of a study that a significant likelihood exists for potential gain, the regulations could require them to report this fact to the IRB. Investigators could then present to the IRB the information they intend to disclose to subjects. This could be approved by the IRB along with written information sheets and consent documents.

Documentation Requirements

Disclosure of potential commercial gain and the use of exculpatory language reinforce the need to accurately document consent. This does not have to be a so-called '(long form" consent; a "short form" consent document would suffice (45 CFR 46.117(b)).

The major difficulty with current documentation is that the IRB has the ability to waive the requirement for signed consent. This can occur when the only record linking the research with the subject is the consent form and the principal risk involved is a potential breach of confidentiality. Similarly, documentation can be waived when a study involves no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context (45 CFR 46. 117(c)).

With the prospect of commercial gain and the use of exculpatory language, some type of documentation could be required to safeguard the rights of all concerned. First, IRBs could be prohibited from waiving consent form documentation when studies involve the prospect of commercial gain or the use of exculpatory language. This solution, however, does not alleviate the concern for a potential breach of confidentiality found in the current regulations. The problem is compounded when an additional consent authorization is required for cases in which commercial gain is discovered subsequent to the first consent. Requiring consent forms in this case could represent a serious concern for subject confidentiality. A breach of confidentiality in this situation could make the subjects a target for unscrupulous persons who for their own financial gain might identify the participants carrying marketable biological substances. A possible solution to this problem is to require researchers to use extra safeguards to maintain confidentiality of research subject information, but this idea may not be realistic.

Another option is to leave the current regulation unchanged, but add a proviso that a waiver

approved by an IRB constitutes a rebuttable presumption of valid consent. This would be important if allegations ever arose claiming that the subject was not informed about commercial gain or that the subject did not waive his right to commercial gain. Unless the subject could rebut the inference of proper disclosure of information or a properly obtained waiver, the presumption of valid consent would stand. If such a recommendation is deemed practical, further review would be necessary to make certain that it does not offend Federal evidentiary provisions.

A third option would be to require a detailed note in the subject's record. This would eliminate the need for consent forms when minimal risk is involved. It also minimizes concern about breach of confidentiality when consent forms are the sole link between the subject and the study. With the use of a carefully designed system of identification codes, a detailed note in the record offers less chance of identifying a subject than does a traditional consent form. A detailed note in the subject's record is also a practical means of documenting disclosures and waivers regarding commercial gain made subsequent to the entry of participants into the study. When confronted with a detailed note in his or her record, the subject will be hard-pressed to prove lack of disclosure or a waiver to commercial gain. A detailed note in a subject's record would have certain advantages over a standardized consent form. For instance, a note could contain information tailored to the specific subject, a feature often impractical in standard forms.

SUMMARY AND CONCLUSIONS

Consent must generally be obtained from patients and research subjects prior to specimen removal for treatment or experimentation. Informed consent represents a two-way flow of information between the physician or researcher and the patient or research subject in order to communicate the facts necessary for the patient to decide on a method of treatment and for the research subject to decide whether to participate in the research.

The common law has developed two different theories of consent: the traditional view, based on the law of battery; and a more modern theory based on the law of negligence. Several States have enacted consent laws, many of which are concerned with setting requirements for information disclosure. Federal regulations provide protection of human subjects in federally sponsored research. The Federal policy requires each research institution to establish and operate Institutional Review Boards that have oversight authority over research using human subjects and sets certain requirements that investigators must follow to obtain informed consent prior to and during research.

Questions arise as to whether disclosing the prospect of potential commercial gain should be required as part of the informed consent process. Arguments favoring such disclosure include the concept that research subjects should have the right to decide what to do with their own tissues and cells, and that current regulations require disclosure of significant new findings developed during the course of research which may relate to the subject's willingness to continue participation. Arguments against disclosure regarding potential commercial gain include the possibility that any commercial gain is highly speculative, that disclosure would hamper a research subject from reaching an informed decision free of the undue influence that monetary gain might provide, and the possibility that subjects might endanger their health and skew research results by hiding facts from researchers so they can participate in research that may provide financial remuneration.

Current Federal regulations contain two provisions that concern the marketing of tissues and cells. The first excludes certain types of specimens (e.g., existing data, documents, records, pathological exams, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects) from

the regulatory requirements. The other provision prohibits the use of exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights. Either or both of these provisions could be revised to achieve certain results, or additional disclosure requirements could be included in the regulations to be used when the prospect of commercial gain is relevant. If additional disclosure requirements and the use of exculpatory clauses are added to the consent process, Institutional Review Boards will have a greater responsibility in oversight of research.

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