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consent to medical care

PROTECTION OF LIFE SERIES

STUDY PAPER

Canada

CONSENT TO MEDICAL CARE

Protection of Life Series

CONSENT TO MEDICAL CARE

Protection of Life Series

A Study Paper prepared for the
Law Reform Commission of Canada

by

Margaret A. Somerville

Une édition française de ce document
d'étude est disponible.
Son titre est:

LE CONSENTEMENT À L'ACTE MÉDICAL

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Available by mail free of charge from
Law Reform Commission of Canada
130 Albert St., 7th Floor
Ottawa, Canada K1A 0L6
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Suite 2180
Place du Canada
Montreal, Quebec
H3B 2N2

Catalogue No. J32-6/2-1979
ISBN 0-662-10452-8

Reprinted 1980, 1981, 1982 and 1983

Notice

The following Study Paper is part of a series of research undertaken by the Law Reform Commission of Canada on protection of life issues.

The author is Professor Margaret Somerville from the Faculty of Law of McGill University. She attempts to clarify the difficult problem of consent to medical acts.

The opinions expressed in this Study Paper are entirely those of the author and do not necessarily represent the views of the Commission or of the Commissioners. The Law Reform Commission of Canada would welcome however any reaction, criticism or comments from the reader. They should be addressed to:

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Introduction

Consent is a legal concept and a factual reality. It has many areas of operation and many purposes, but in the medical situation it has the primary functions of regulating risk-taking and controlling invasion of privacy. The way in which this regulation and control is effectuated in any particular medical circumstances, will be determined firstly by which principles of the legal concept of consent are applicable and by their substantive content, and secondly by the reality of the factual presence of consent. This paper seeks to analyze the legal and factual basis on which consent rests, for the purpose of establishing a comprehensive picture of the doctrine's operation in the medical relationship.

Consent is a fundamental concept in both criminal and private law, and in Common Law and Civil Law legal systems. Thus it is necessary to explore each of these dimensions to assess accurately its sphere of influence in Canadian Law. This means that it is impossible to conduct a comprehensive analysis of the doctrine and, at the same time, respect the traditional division of legislative powers under the *British North America Act*.¹ In other words some matters which are purely of provincial jurisdiction must be considered if the total concept of consent is to be developed as an analytical tool. That this development is necessary at a Federal level, for instance for criminal law purposes, can be demonstrated by a fundamental example: without consent, except in a justified situation of emergency, every medical operation would be an assault. Thus consent is an essential part of the criminal law. Although, from a Federal jurisdictional point of view, it would be desirable to approach an analysis of consent through the criminal law, most of the doctrine and case-law relevant to the doctrine's application in the medical relationship is found in the private law sphere. For this reason the plan of this study is to first examine consent as part of the private law medical relationship, and then to assess the role of the criminal law in controlling this relationship particularly the part that the doctrine of consent plays in such control.

As well as crossing federal-provincial jurisdictional barriers, the concept of consent may be treated comparatively in the more traditional comparative law sense of this term. This is a particularly fruitful exercise as consent is a concept subject to recent and still developing evolution, especially in the medical relationship, in Canada and in other jurisdictions which are comparable with Canada.

Consequently, the materials which will be used in this study are comparative in more than one sense and are gathered in Civil Law from Quebec and France, and in Common Law from Common Law Canada, England, the United States of America and Australia.

CHAPTER I

Fundamental Principles Underlying Consent

A. RIGHT OF SELF-DETERMINATION

The right of self-determination expresses the principle, or value choice, of autonomy of the person. Mill² espoused this principle when he reasoned that one is only justified in intervening with the liberty of another for self-protection as did Devlin³ to the extent that he claimed each must be allowed to pursue his or her own way. Other authors⁴ put forward self-determination as one of the basic principles of a democratic society and this is expressed in the belief that the values of democracy are individualism, freedom and personal dignity⁵ Freund⁶ sees the individual as having a qualified right of free choice and self assertion⁷ and Capron⁸ regards a competent person as needing the law's protection of his interest in being able to choose. Fried envisages as the "ideal good", a social union of "autonomous person[s]" in which "each person's individual self-respect and sense of integrity are fostered and reinforced by the conditions of mutual cooperation in which the value and integrity of others is simultaneously affirmed".⁹ Applied to the medical relationship between doctor and patient, this postulates a complex balance between personal autonomy and the limits of this right in respect to one's own, or the use of, another's body.

Some sociologists have suggested¹⁰ that the reason that autonomy has heavy value-weight in a society, for instance the American one, is cultural. American society has high regard for an active, rationally based, mastery of life, and for any achievement that blends individualism with a humanitarian sense of social responsibility. Hence, in American society, it is an accepted and acceptable

notion that one may exercise one's autonomy to become, for example, a volunteer subject of medical research.

The commentators referred to so far, are all from Common Law jurisdictions. One finds, on examining the writings of Civil Law jurists, that the principle of self-determination is also present, but not so much at the apex of the pyramid of values. Decocq¹¹ expresses respect of autonomy as an influencing, but not overriding, value in any decision. Kornprobst¹² sees the value as even more subordinate to other principles.

In a book on socialist law relating to the person, Nizalovsky¹³ compares the approach of the Civil and Common Law systems to the principle of autonomy. He finds a wider prohibition on self-mutilation in Civil Law and, to some extent, a contrast in Common Law as expressed by the latter's belief that each man is master of his own body. The former view may be seen as an expression of paternalism, which is the opposite of self-determination. In a paternalistic approach the motive is to do good to the individual, which, negatively stated, is also to prevent harm to him. The motive behind self-determination is the right *per se* and, outside of seeing the right itself as a benefit, encompasses neither motives of good nor harm regarding the individual. The motive behind any limitation to the latter principle may be seen, consistently with the principle itself, as that of preventing harm to society, not to the individual as such.

This right to self determination may, to some extent, depend for its existence on whether one has an open or closed legal system. In an open legal system all that which is not prohibited, is permitted, which accords with a principle of self-determination, subject to some limitations. In a closed legal system all that which is not permitted, is prohibited and, thus, the right of autonomy is not *sui generis*, but given by law, and, at least to that extent loses some of its own internal, autonomous characteristics.¹⁴ It is also, at least theoretically, more limited in its external operation, as any novel situation will cause prohibitions rather than permissions to arise.

Although differing in theory in their approach to the autonomy value, it is more difficult to assess how far apart the Civil and Common Law are in practice regarding this principle. The right to self-determination has been reaffirmed in many cases at Common Law. Perhaps the most famous and often quoted rendition, is that of Mr. J. Cardozo in *Schloendorff v. N.Y. Hospital*,¹⁵ that: "Every human being of adult years and sound mind has a right to determine

what shall be done with his own body.’’ Prosser supports this view: ‘‘It is a fundamental principle of the common law that *volenti non fit injuria*—to one who is willing no wrong is done. The attitude of the Courts has not, in general, been one of paternalism. Where no public interest is contravened, they have left the individual to work out his own destiny and are not concerned with protecting him from his own folly in permitting others to do him harm’’.¹⁶ So do such commentators as Skegg,¹⁷ who concludes that the Common Law places great importance on the individual’s interest in deciding for himself what is done to his own body.

There may, however, be reason to question the true extent of the principle, as it is only probable, and not certain, that the Common Law will uphold the right of a fully competent adult to refuse treatment.¹⁸ Spece¹⁹ states that human autonomy is the value which is presumed to exist in establishing a right *against* treatment and in the fact that this can be waived to allow treatment.²⁰ But the operation of this right is not absolute according to Fleming,²¹ who initially justified a doctor acting in an emergency without the consent of the patient, or his relatives where applicable, on the basis that ‘‘the law plac[es] a higher value on the preservation of life than on the inviolability of the human body’’.²² Interestingly, Fleming has altered this justification in a very recent edition of his work, to one based on ‘‘the humanitarian duty of the medical profession’’.²³ This is not inconsistent with the previous justification, but probably some inference of doubt as to the validity of the former must be drawn from its omission.

The previous discussion raises the question, what is the relationship between autonomy and inviolability? Autonomy allows the will of the person to dominate, and the factual result arising from the application of this principle coincides with that of inviolability when the expression of will is to protect self-integrity. Inviolability, on the other hand, may have two contents of meaning. It may connote that one is not justified in treating another without his consent, but is justified in doing so with it, in which case it is merely a particular application of the autonomy principle; or it may indicate a principle that protects a person’s physical and mental integrity against non-beneficial acts by the person himself, or others, when it is a preservation of life value.

Consequently, under a principle of autonomy, which includes inviolability in the first sense discussed, one could properly allow a personally non-beneficial act which would be prohibited under a

ruling doctrine of inviolability in the second sense. Fleming, in the earlier statement quoted, is using the principle of inviolability in the first sense, and therefore sees a conflict between touching without consent, which this principle prohibits, and saving life when the unconsented to touching is necessary to this end. It is preferable, I submit, to define the principle of inviolability in the second way, which is how many Civil Law jurists see it,²⁴ and as having the purpose of preserving life, health and well-being. The first sense of the principle of inviolability is not lost, but would still be, and perhaps even more effectively implemented under the doctrine of autonomy. Such an approach leads to a clearer analysis especially in areas where values conflict and thus must be hierarchized, as it separates the preservation of life value from the autonomy one. In using the terms as defined, Fleming is in reality saying that the Common Law ranks preservation of life above *autonomy* and one could add, that one of the values supporting this preservation is inviolability.

This proposition needs further investigation however, as Fleming makes it clear that both the earlier and later justifications he has proposed for medical interventions without the consent of the person involved, refer to a conflict of the values of autonomy and preservation of life in a situation where the person is factually unable to consent, that is, when there is no possibility of exercising personal autonomy. In this case, no matter how it is justified, preservation of life overrides a strict application of the doctrine of autonomy²⁵ and this result also coincides with the aim of the principle of inviolability. But what is the position if the patient refuses necessary treatment? In the previous edition of his text, Fleming had replied that the policy of life preservation "may be so strong as to justify medical treatment . . . even *against* the wishes of the patient in order to save his life . . .".²⁶ This has been amended in the latest edition to read that "[i]t is extremely doubtful . . . whether our law would permit such an intervention, even to save life, against the declared wishes of a mentally competent adult or guardian of a minor".²⁷ Thus when a person is capable of consenting and refuses to do so, the conflict between the values of self-determination and preservation of life becomes overt, and the most accurate statement one can make with respect to the law is that it is far from clear which value a Common Law Court will support as prevailing.²⁸

Kornprobst²⁹ states the Civil Law approach when he argues that one can treat without consent, on the basis that the health of the individual is a social good and it is a crime against society to refuse

such treatment. Further (he argues), the doctor's "right to cure" gives him the right to act without consent. These statements bring into focus the relationship between self-determination and consent. The latter of these two concepts will be analyzed later in this paper.³⁰ This relationship exists because consent is the legal mechanism by which the principle of autonomy is implemented and respected and, to the extent that consent is not required, autonomy is not the dominant value. The question which arises with regard to autonomy is, are there any limits to the type of procedures to which one may consent or which one may refuse. This is to be distinguished from the question of how, having established the limits if any, one effectively consents.

It is in the area of determining to what procedures one may consent, rather than which one may refuse, that limitations to the principle of autonomy appear most obviously to be recognized at Common Law. It can be argued that any such limitation is not an exception to the rule of self-determination. Rather the limitation on the right falls within the autonomy principle itself, as formulated by Mill,³¹ if it is justified on the basis that it is necessary for the "self-protection" of society. Here one can see that the difference between the Civil and Common Law is one of degree, rather than kind as the same justification is being used. Kornprobst³² for example supports imposing necessary but refused treatment on the basis of social good. The Common Law will arguably not impose treatment, but, one step removed and like the Civil Law, refuses to allow consent to procedures it sees as harmful to the collectivity.³³ The strongest example of this principle is the rule that one cannot consent to a criminal offence.

In Civil Law jurisdictions, apart from specific legislative provision, the breadth of the right to consent to bodily interference is, *prima facie*, limited to personally therapeutic interventions,³⁴ although justifications may arise under the doctrine of necessity. For example, until recently, when legislation on living-donor, organ transplants was introduced by the French Parliament,³⁵ operations on such donors were justified on the basis of "l'état de nécessité" of the recipient.³⁶ The right to consent is broader at Common Law in that non-therapeutic medical intervention is not *per se* illegal, and is consented to and carried out regularly, but the legal limits are unclear.³⁷

In summary all relevant jurisdictions recognize a principle of autonomy or self-determination, the limits of which depend on public

policy, and which are most strongly expressed in the criminal law. Traditionally these limits are wider at Common than Civil Law but in practice, except for the prohibition of non-therapeutic medical experimentation in France, the actual limits may not be very different. Further, one must recognize that what those limits are, at any time, is a reflection, basically, of the culture in which they exist³⁸ and hence they are not static.

Finally one should note a value which may be confused with self-determination, and which is highlighted by Bereano,³⁹ who makes the point that “*participation* in decision-making” is a value in itself. However this is a different value from self-determination if it envisages shared, rather than sole decision-making authority regarding oneself. The difference arises if one intends by the words “decision-making” to mean *decision result* in the sense that some form of majority will prevail, rather than the *decision-making process* which is consistent with a policy of self-determination, which requires information input from other sources.

B. RIGHT TO INVIOIABILITY

As already discussed⁴⁰ this is a principle related to autonomy, and in the Civil Law to some extent governs aspects seen under the doctrine of autonomy in Common Law. But most importantly, regardless of jurisdiction, this is one of the most fundamental principles underlying the criminal law.

From the discussion on autonomy I suggest one may conclude that the Common Law envisages this right as having schizophrenic attributes. It is possible to either employ it as a positive, self-protective institution or to use it in a negative, self-destructive way. Further it appears that the Common Law generally assumes that a person will act in his own “best interests” and that this will usually be self-protective viewed subjectively, and ideally objectively as well. Consequently the right to inviolability of the body should be seen as falling within the positive aspect of autonomy and as limited to the extent that the negative “anti-life-preserving” aspects of autonomy are validly exercised and take precedence.

The Civil Law is less inclined to leave to chance the decision to act in a self-protective way and has a well developed doctrine of inviolability of the human body, which arises from a basic moral

presupposition of respect for human life. Laget⁴¹ refers to this as the “most fundamental rule” and Jonas⁴² as the “primary rule” needing no justification but rather exceptions to which must be justified. Mayrand⁴³ takes a similar approach when he says that the principle is not absolute, but can be derogated from in the interest of higher values—for example for reasons of love or altruism and, naturally, in recognized self-interest such as therapeutic surgery. Decocq regards “le caractère sacré de la vie humaine” as giving rise to this right and duty of inviolability, which he describes as “le respect de la personne humaine”.⁴⁴ It is worth noting that Decocq recognizes “le respect de la volonté humaine”,⁴⁵ that is the right to autonomy, but only in so far as it applies to support life.

The same view is expressed by Mayrand when he says: “C’est précisément dans le principe de l’inviolabilité de la personne que puise la justification d’une intervention imposée. L’inviolabilité de la personne a pour but sa protection; or, les droits doivent être exercés dans le sens de leur finalité. Ce serait fausser le droit à l’intégrité corporelle d’un malade que de lui permettre de l’invoquer pour faire échec à ce qui peut conserver sa vie et, par la même, son intégrité essentielle”.⁴⁶ In order to complete the picture, one must acknowledge that the matter is not fully settled in Civil Law. For instance Savatier *et al* seem to consider the person’s will as dominant and that the inviolability principle supports this when they say “le premier attribut juridique de chaque personne est l’intangibilité de son intégrité corporelle et des principes de sa vie. Il n’y peut être touché, même par le médecin, qu’avec son consentement”.⁴⁷

Thus one may debate whether the purpose of the inviolability principle is to preserve autonomy, in which case it parallels the common law self-determination value, or to preserve life and health when this aim will justify overriding a patient’s will which is to the contrary. In the former case the principle, consistently with the aim it is designated as serving, will be absolute; on the same reasoning, in the latter case, it will be only relative. This distinction allows one to support the view that the principle of inviolability does apply at Common Law but under an autonomy preserving rationale, whereas at Civil Law it applies in its life and health preserving capacity.

Nerson⁴⁸ approaches these principles of autonomy and inviolability from a slightly different and instructive aspect. He sees the “valorisation” of the body as arising from an “inspiration individualiste” and underlining “la nécessité de protégé l’intégrité physique de l’individu”.⁴⁹ In classical Civil Law the body was

neglected, but modern Civil Law has developed obligations of security, “dans une jurisprudence enfin consciente de la nécessité de protéger les personnes”.⁵⁰ Now the problem is how far one can derogate from this principle for such purposes as non-therapeutic experimentation, living-donor organ transplantation, or euthanasia, for, as Nerson says, “le principe d’inviolabilité n’assume pas seulement la défense du corps contre les atteintes des tiers, mais aussi contre le pouvoir de disposition de l’individu lui-même; des restrictions sont apportées à l’autonomie de la volonté; l’inviolabilité a pour conséquence l’indisponibilité du corps humain”.⁵¹ In order to assess the current situation one must balance this statement against the fact that there has been “[un] recul du principe de l’indisponibilité du corps”.⁵² The problem that now faces each jurisdiction is to work out the limits to which this recoil ought to be allowed to extend, which is regulated through the doctrine of consent and its operation in criminal and private law.

CHAPTER II

The Doctrine of “Informed” Consent

“Informed” consent is a private law doctrine which has become so significant to any discussion of consent that it must be investigated first.

The content of the doctrine of “informed” consent can be seen within three main overlapping areas: capacity or competence, information or knowledge, and voluntariness. In the first part of this section capacity will not be in issue, as I will deal initially only with the “normal, capable, adult subject” with respect to whom a presumption of both legal and factual capacity operates. Information and voluntariness, on the other hand, are both relevant considerations with respect to such persons and will be examined.

“Informed” consent is probably the single most discussed topic in medical law, to such an extent that at times, it seems to overshadow everything else. This is dangerous, as it engenders a feeling that, provided one ensures that “informed” consent is obtained, the situation is legally and ethically acceptable. Such may not be the case and I prefer to see “informed” consent as a necessary, but insufficient protection of the normal adult subject, operating within a framework of protections.

The two platforms from which one often views “informed” consent are informing and consenting, and I will look at these first. Then one must study the effects of mistake, deception, coercion, or duress, on the validity of the consent. Such a comprehensive enquiry

covers all the positive and negative aspects of the requirements of information and voluntariness. Additionally, under the duty to inform the patient, I will examine the duty to hand over medical records, which is a duty to inform, but not for the purposes of “informed” consent. Then, in the following section, I will examine the relationship between consent and the increasingly recognized right to privacy.

A. INFORMING THE PATIENT

1. The duty to inform the patient or research subject for the purpose of obtaining “informed” consent^{52a}

This duty is related to assessment of risk. This is so because assessment of risk defines some of the factual content of the information which must be imparted and, in the therapeutic situation, may affect the extent of the duty to inform. The duty to inform the patient is also part of the fiduciary duty of a doctor, that is, part of the doctor’s special duty of care and trustworthiness.⁵³ Outside a fiduciary relationship, although there are obligations not to misrepresent or deceive, there may be no positive obligation to disclose, and a person’s consent to an act is usually valid when he knows the nature of the act, although he may be ignorant as to its consequences.⁵⁴ The fiduciary relationship changes this situation through its *uberrimae fidei* effect, which imposes a duty on the doctor to ensure that the patient is informed to a much wider extent than just with respect to information relating to the nature of the act, in default of which any consent given is inoperative.⁵⁵

There are two major points to be taken into account in formulating the duty to inform the patient. Firstly the conduct which is legally required to fulfill the duty to inform must always be assessed *in relation to the circumstances* in which it is applicable and, therefore, according to whether the situation is non-therapeutic or therapeutic. In the latter case, the degree of need of the patient for the treatment, the probable effect of the information on the patient’s state of health, the magnitude of the harm threatened by the medical intervention, and the chance of the harm occurring, are all relevant factors affecting the standard applicable to the duty to disclose. These variables are related, so that the greater the patient’s medical need, the more the chance the information will harm his health, the less the magnitude and likelihood of occurrence of the risk, the more

justification the doctor has in not fulfilling his duty to otherwise fully disclose the nature and possible consequences of the intervention.⁵⁶

Secondly, I suggest, that in order to decide the content of the duty to obtain “informed” consent in any particular situation, it is relevant to ascertain the purpose one seeks to achieve by requiring it.

One may explain the purpose of “informed” consent from many viewpoints which are discussed in detail later.⁵⁷ But from the aspect of disclosure, there is a need for information in consent in order to respect non-physical aspects of persons—their thought-process and therefore their humanness.⁵⁸ Generally authors⁵⁹ describe the right being protected by consent, which is but one aspect of the total purpose consent may serve, as the right of the patient to decide for himself what should happen to him, that is the protection of his integrity or inviolability, and autonomy.⁶⁰ As proposed before,⁶¹ these aims are not always mutually compatible, and in defining the duty to inform, one may as in other areas have to choose between them. Although autonomy mandates full disclosure and understanding before consent is given, this could in fact be harmful to a patient’s state of health. Disclosure could threaten the physical or mental well-being of the patient, that is it may, arguably, not respect his right to inviolability whereas non-disclosure could be construed as a threat to his autonomy. In these circumstances both the Civil and Common Law allow an exception to the duty to inform, often called a “therapeutic privilege”.⁶² It is obvious when one understands the justification for this exception that it could only apply to an intervention for the therapeutic benefit of the patient, and not for instance to non-therapeutic medical experimentation. This is undisputed in the literature.⁶³

This is a specific example, but in general biomedical research on persons is one of the medical situations in which the consent issue is brought most sharply into focus. Therefore it is fruitful to examine biomedical research in relation to the duty to inform the patient.

Slater v. Baker,⁶⁴ the earliest recorded Common Law case which makes mention of experimentation in medicine, actually proposed as the purpose of requiring disclosure to the patient, “so the patient can take courage”. It is interesting to ponder how applicable today such a reason for requiring the patient to be informed might be. After all, in knowing more we know that we know less of the total that could be known, and although the increase in knowledge means less risk from disease, at the same time it creates iatrogenic risk.

Paradoxically, it also means that it may be harder for a patient to "take courage" in the face of what he knows, or is told, is unknown.

On examining codes and guidelines as well as some subordinate legislation relevant to human medical experimentation, one finds frequent and consistent reference to a duty to inform the patient. The Nuremberg Code requires "full knowledge";⁶⁵ the United Kingdom Medical Research Council insists on "adequate explanation";⁶⁶ the United Kingdom Royal College of Physicians calls for a "full explanation";⁶⁷ the American Medical Association requires "disclosure . . . a reasonable explanation . . . and an offer to answer any inquiries";⁶⁸ the Declaration of Helsinki says that the subject must be "adequately informed . . .";⁶⁹ the Medical Research Council of Canada states that "accurate and complete information" should be given;^{69a} the United States F.D.A. regulations require that the researcher "inform" the patient;⁷⁰ that country's D.H.E.W. regulations specify that the research subject's "informed consent" be obtained, which is defined *inter alia* as "a fair explanation . . . a description . . . a disclosure . . . an offer to answer any enquiries . . . and an instruction . . .";⁷¹ and "La Charte du Malade Hospitalisé" of France, states patients must be given "les information sur leur état qui leur sont accessibles".⁷²

The documents cited here are relatively modern and demonstrate that in all jurisdictions, even the ones that show early recognition of this duty to inform a patient, there has been recent evolution of either the duty itself where it was not previously acknowledged, or its content where it was. This reflects a change in attitude which can be gauged by realizing that the Hippocratic Oath, the most universal medical ethical guide until recently, had no such requirement.⁷³ As late as 1957, a Quebec commentator wrote that a doctor could presume consent to ordinary medical treatments and there was no need for him to give information to the patient unless asked for it.⁷⁴ Boucher *et al.*,⁷⁵ also speaking of the situation in Québec in this respect, cite a case, *Brunelle v. Sirois*,⁷⁶ which states that in this jurisdiction a tendency to give more information to the patient can be traced during the 1960s. Similarly, Boyer Chammard and Monzein, writing of France, note that the necessity for a clear consent, including a duty to inform, only developed in the 1950s in that country.⁷⁷

It seems that the duty to inform a patient was recognized earlier and developed more strongly in Common Law.⁷⁸ Although this phenomenon is undoubtedly just one expression of a complex of

sociological factors, which includes the community's perception of the role of a physician, it is possibly related to the dominance of the autonomy principle in those jurisdictions in combination with a less forceful approach to the inviolability of the body rule with respect to non-therapeutic interventions. This approach was premised on a philosophy that the person was his own best protector and clearly, in order to be this, he needed to be properly and adequately informed, especially in the medical situation where there is a knowledge and competence gap creating inequality.

The question now is what is the extent or scope and depth or content of the duty to inform or, asked another way, what is the standard applied to determine whether a doctor has fulfilled this duty?

Firstly there is a fundamental choice which must be made between seeing the obligation as honoured by giving the required information to the patient, and on the other hand requiring that the informant ensure either objective or subjective comprehension by the patient.⁷⁹ The latter is obviously the most demanding and difficult criterion, but it alone fully maintains the concept that consent involves understanding. That the patient is understanding of the information required to be given to him under the doctrine of "informed" consent is necessary for a legally valid consent, appears to be more and more accepted,⁸⁰ and is strongly recognized throughout two recent Canadian cases, *Kelly v. Hazlett*⁸¹ and *Reibl v. Hughes*.⁸² In the former case the patient's apparent consent was held to be vitiated specifically because the plaintiff did not understand the risks and the doctor knew this.⁸³ In the latter case the doctor was held liable in battery and in negligence, the Court stating, with respect to liability in battery, that "a physician [has] a strict duty to explain to his patient, in language which the patient can understand, the essential nature and quality of the treatment he is to undergo";⁸⁴ and, in relation to negligence liability, that the doctor must "take sufficient care to convey to the plaintiff and assure that the plaintiff understood the gravity, nature and extent of risks specifically attendant on the [procedure]".⁸⁵

The most frequent argument against a requirement of understanding by the patient is that it is impossible to attain with non-medical persons. In this respect Garnham⁸⁶ makes a worthwhile distinction when he says that there is a difference between requiring understanding of technical details and comprehension of possible medical and social consequences. The latter should be required in

relation to all medical interventions, but in certain cases it may be crucial to legal and ethical validity. The point is that if, for instance in a non-therapeutic research intervention, a person does not understand the possible risks of what he is undertaking, he is not a volunteer. As a consequence, unless there is some other justification applicable to the intervention, one has moved outside any altruistic rationale and moral justification based on this, for allowing experimentation to take place. Thus it seems comprehension should normally be required as an element of the duty to inform and be mandatory when the situation is non-therapeutic, which is to propose a governing concept of "informed and understanding" consent.⁸⁷

It is, however, legally difficult to monitor a totally subjective requirement of comprehension by the patient. An intermediate position has been suggested by Capron, that "the physician could be held responsible for taking reasonable steps to ascertain whether the information presented has been understood . . .",⁸⁸ that is a test of "apparent subjective understanding" by the patient of the information required to be given to him.

Thus in setting a standard to which the physician must adhere in relation to understanding by the patient of the information he is given, one has the choice between requiring: actual subjective understanding; apparent subjective understanding; and objective understanding, that is, the "reasonable patient" would have understood, whether or not the particular patient did.

If one chooses "apparent subjective understanding" as the standard, a similar standard should equally be applied to govern which information should be withheld. When in other words it may be a breach of duty to give the patient certain information. This occurs if the doctor knew, or ought to have known if he had taken reasonable steps to find out, that disclosure of the information would harm *that patient*.⁸⁹ Further, it is worth considering here whether there is at least a difference in nuance between a doctor's duty to withhold information and his doing so pursuant to a claim of "therapeutic privilege". "Therapeutic privilege" is not a wide doctrine and probably only applies when to disclose the information would cause recognized physical or mental harm to the patient.⁹⁰ Yet it possibly applies as a justification for non-disclosure more extensively than only when the doctor would have breached his duty of care, or committed fault, by making a disclosure. Clearly, however, there is a central core where both concepts are coexistent.

The important points to underline are that the doctrine of “therapeutic privilege” applies where its conditions precedent are fulfilled, within the “pure” therapy situation, that it never applies in non-therapeutic interventions,⁹¹ and only rarely, if ever, does it apply in therapeutic research;⁹² nor could a doctor breach his duty of non-disclosure to the patient or research subject by informing him of a risk or consequence of a medical experiment.

One must now examine the extent of the duty to inform, that is the range of factors which must be disclosed, and how in any particular situation this is to be assessed. The most frequently formulated general tests are described in terms of materiality or relevancy: that is either the factors must be disclosed which are subjectively material⁹³ or relevant⁹⁴ to that patient in deciding whether to participate in that procedure;⁹⁵ or objectively, the doctor must disclose what a reasonable patient in those circumstances would want to know.⁹⁶ This approach, whether the subjective or objective standard is used, marks a change from the extent of the necessary disclosure being determined by the medical profession, or according to medical custom, to assessment by lay standards. In the United States of America, the most noteworthy case demonstrating this change is *Canterbury v. Spence*.⁹⁷ Such a development, if it has occurred in other Common Law jurisdictions, is not documented as yet in their reported cases and this is clearly an unsettled area of law in all jurisdictions.

It is necessary to consider, however, whether this last statement needs modification in relation to the jurisdiction of Ontario, in view of the two recent cases on consent to medical interventions mentioned previously. These are interesting but complicated with regard to who sets the standard for the content of the disclosure. In the earlier one, *Kelly v. Hazlett*,⁹⁸ Mr. J. Morden, in specifying tests to determine what information must be disclosed by a doctor to avoid liability, firstly in assault and battery, or secondly in negligence, says that the former requires disclosure of “the basic nature and character of the operation”⁹⁹ and the latter of “collateral risks”,¹⁰⁰ with only the latter being “determined with the assistance of expert medical evidence on what would be the proper scope of disclosure”.¹⁰¹ In regard to setting the standard of disclosure for this latter class of risks, any analogy to the American case-law, which holds that the content of “the duty is based upon the notion of what a reasonable patient might be expected to wish to hear in order to make up his mind”,¹⁰² was expressly rejected. It seems, however, that a “lay” standard would apply to disclosure of risks in the former class, as a

necessary implication from the fact that expert evidence is not needed with respect to these.

The difficulty thus becomes one of characterizing any particular risk within the suggested division, in advance, in order to determine whose standard applies, the patient's or the reasonable patient's¹⁰³ on the one hand, or the doctor's on the other. This proposed division may cause problems in prospective interpretation of the conduct required by law of the medical profession with respect to disclosure;¹⁰⁴ it could also, rather arbitrarily, alter liability through its effect, which the Judge recognizes, on "matters [such] as the incidence of the onus of proof, causation, the importance of expert medical evidence, the significance of medical judgement, proof of damage and, most important of course, the substantive basis upon which liability may be found",¹⁰⁵ which are "more than . . . matter[s] of mere academic interest".¹⁰⁶

Likewise there is controversy in the Civil Law as to what must be disclosed to a patient¹⁰⁷. The generally accepted formula in France appears to be that the information must be "simple, approximative, intelligible et loyale".¹⁰⁸ Vidal and Carlotti¹⁰⁹ say this means the patient must be told the essential elements which are determinative of his choice. Mazeaud and Tunc¹¹⁰ note that "il suffit de lui donner une idée raisonnable de la situation et de lui permettre de porter un jugement raisonnable." These statements are consistent with, and expositive or determinative of, the general attitude of French jurisprudence towards the duty of the doctor to inform the patient. This appears to be less stringent in scope, content and application than in either Quebec or Common Law North America.¹¹¹ This assessment of the French law must be balanced, however, against the emphasis in Civil Law on the patient understanding the information which is given¹¹² which, within the scope of the disclosure required, is a more demanding standard than that often applied at Common Law. This approach may indicate a preference for subjective standards, which is generally true in Civil Law jurisdictions including Quebec, and consequently that the test of relevancy or materiality of what must be disclosed is subjective, rather than objective. This really means fulfillment of the duty is assessed from that particular patient's standpoint and not from that of a reasonable patient, nor from that of his doctor, nor of a reasonable doctor.

Although such a standard is the ideal, it may place an unfair burden on physicians, as well as giving any injured patient the advantage of "hind-sight" in claiming that an undisclosed risk was

material to him, and I suggest the test of disclosure should be based on the standard of what a reasonable patient in those circumstances would consider to be relevant information, with an additional subjective test that if the doctor knew, or ought to have known, that certain other information was considered relevant by a particular patient, than this as well must be disclosed.

These are rather general formulations of the duty to disclose, which are necessary if only to indicate that there are several possible approaches to filling in the content of this duty, which content is continually changing and, further, must be adapted to each set of circumstances. It is possible, however, to formulate a general but not exhaustive substantive standard and to name some more particular instances of the type of information which should be given to a patient. The general rule is that the disclosure must at least include a fair and reasonable explanation of the nature of the procedure and of its risks.

With respect to explaining the nature of the procedure this will usually be accomplished by describing, in general terms comprehensible to the patient, the procedures to be carried out and their inevitable consequences as compared with their risks.

In regard to risks, obviously if these are not known they cannot be disclosed, but usually the very fact that there are unknown risks should be. This is probably the same duty as that formulated by the Court in *Fiorentino v. Wenger*¹¹³ when it held the doctor was in breach in not disclosing specifically that the proposed procedure was novel and unorthodox. Waltz and Scheuneman¹¹⁴ acknowledge such a duty to reveal that there may be unknown risks, but go even further than this and postulate a duty of "risk discovery" in innovative therapy, which amounts to applying, and complying with, the ethical-scientific principles such as prior animal experimentation, bio-statistical assessment, and "herald" or cooperative trials. In other words disclosure that all risks are not known does not exempt a physician from liability for not disclosing risks which should have been known. It may even be that a certain degree of lack of medical-scientific knowledge of risks may make "informed" consent impossible, although all prior ethical-scientific requirements have been complied with and disclosure made of the fact there are unknown risks. Such was a holding, *inter alia*, of the Court in the *Kaimowitz Case*,¹¹⁵ in prohibiting a particular experimental psychosurgical procedure.

The most comprehensive statements of the categories of risk that must be disclosed prior to a medical intervention are set out in relation to human medical experimentation in the Regulations of the Department of Health Education and Welfare (D.H.E.W.)¹¹⁶ and the Food and Drug Administration (F.D.A.)¹¹⁷ of the United States of America.^{117a} But, even these I submit, are still incomplete, at least for the non-therapeutic situation. For example the D.H.E.W. definition, which is the more generally applicable of the two, states that “[t]he basic elements of information . . . include:

- (1) a fair explanation of the procedures to be followed, and their purposes including identification of any procedures which are experimental;
- (2) a description of any attendant discomforts and risks reasonably to be expected;
- (3) a description of any benefits reasonably to be expected;
- (4) a disclosure of any appropriate alternative procedures that might be advantageous for the subject;¹¹⁸
- (5) an offer to answer any enquiries concerning the procedures; and
- (6) an instruction that the person is free to withdraw his consent and to discontinue participation in the project or activity at any time without prejudice to the subject.”

The F.D.A. Regulations,¹¹⁹ which govern only experiments with “investigational drug[s]”, expressly require a patient or subject to be informed that he may be used as a control, if this is, in fact, the case. Such a disclosure requirement, as well as the more specific ones relating to “the nature, expected duration, and purpose of the administration of [the] . . . drug [and] the method and means by which it is to be administered . . .”,¹²⁰ are, presumably, included within the requirement of “a fair explanation of the procedures to be followed” of the D.H.E.W. regulations.

Extensions to the D.H.E.W. definition which have been suggested, include a duty to disclose the overall purpose of the research,¹²¹ which would be particularly important if medical research were not restricted to medical purposes.¹²² It is possible that some patients or subjects would agree to participate in research having one general purpose but not another, even if both of these are medical: for example a pregnant woman may agree to be a subject of research aimed at improving the well-being of foetuses, but not to the same research if it was designed to advance abortion techniques. It is surely for subjects to decide what purposes they choose to promote by their participation.

Connected with this duty to disclose the general purpose of a medical research undertaking, is a subsidiary one of disclosing the

source of the research funding. This is a safeguard which would be effective in some circumstances, in putting subjects on notice of questions they may want answered before agreeing to participate. Another valuable disclosure for similar reasons of "giving notice", is that suggested by the World Health Organization¹²³ in relation to the conduct of drug trials, which is that additional remuneration of investigators for conducting research be disclosed to subjects.

I would suggest that it is not sufficient to disclose that alternative therapies are possible, but that the doctor must indicate that he will at least make his best efforts to see that these are made available to the patient, and further, that if one of the treatments is experimental and the patient decides to refuse this now, he would retain the option to consent to it at a future time.¹²⁴ Such provisions mitigate against any coercion that the patient may feel if he imagines that a refusal of experimental treatment will leave him without any, or adequate, treatment, or close off his options permanently. That is, not only a right to rescind consent must be given, but also a right to rescind a refusal of consent should be considered.

Other recommendations¹²⁵ in relation to disclosure of information to medical research subjects are that it should include: the reason for selecting that person as a subject and a note that the potential subject can decide not to participate without prejudice; promises of confidentiality, of compensation, or of non-compensation if this is applicable,¹²⁶ and that additional costs to the subject due to his participation will be met.

The way in which required information is delivered to a patient is important from several aspects. These include avoiding coercion and aiding understanding by the patient, not only understanding of the content of the information, but also of his rights in the particular situation, especially those rights not referred to expressly. This means not only speaking to the patient in his own language, but the words selected within the language used must be simple and clear, without mandatory overtones whether overt or subtle, and invitatory, that is expressing that the person has the right to make a decision whether to submit to treatment or not.¹²⁷ In the medical research context, but equally applicable in the "pure" therapy situation, Hershey and Miller¹²⁸ suggest that this approach can be implemented by referring to the patient's rights in the second person and the researcher's duties in the first person, for example: "You are completely free to withdraw at any time from the experiment", and "if you have any questions, we expect you to ask us", to achieve the

maximum personal impact of the respective rights and duties involved.

Thus there are more problems involved in giving the patient information than just deciding what must be said. It is also a question of how, where, and by whom the information is to be given if disclosure of information, a procedure designed to protect the patient or subject, is not itself to be used as a coercive tool.

As to how and where the information should be given, Martin *et al*¹²⁹ suggest that the disclosure process, as well as the consent which may eventuate from it, must be viewed within a "social context". This means one must take account of possible coercive elements in the setting, such as peer group influence or, to repeat, even such simple factors as the tone of the language used to communicate the information and whether this is framed as an invitation, or gives an impression that consent is presumed.¹³⁰ The form and style that a disclosure takes are of even further significance as there is evidence¹³¹ that overwhelming a patient with information may decrease his degree of comprehension. In this respect probably the generally applicable ideal is simple, comprehensive language, presented both orally and in writing, with provision of adequate opportunity for questioning by the patient. At least in the non-therapeutic research situation and possibly where appropriate in other instances, there should be a mandatory delay between presentation of the information and obtaining of consent. Gray,¹³² after a very detailed empirical study on consent in the therapeutic medical research situation, concluded that the place where the information was delivered was important to the degree of comprehension by the patient, and it affected his decision whether or not to participate in a medical experiment. For example, a patient who has been admitted to hospital may feel less able at that time to refuse to participate in an experiment than he would have if he had been asked one month prior to admission.

As to who should do the informing there are several factors to be balanced: there is a danger of leaving a patient uninformed when the duty to obtain consent is delegated to a subordinate;¹³³ on the other hand, the more dissimilar a subject is from the physician in terms of education, race, status and economic position, the more likely is the subject to be unaware of the nature and purpose of the medical procedure.¹³⁴ Barber *et al*¹³⁵ suggest that physicians, especially when conducting research, use mechanisms which protect them from emotional involvement with subjects by limiting their contact with

them, and one of these is having a nurse or intern obtain consent. To overcome this situation it should at least be mandatory for a physician to personally satisfy himself that "informed" consent has been obtained. Ideally this should involve some personal interaction between him and the patient, which will act as a protective mechanism for that patient. This may be enforced legally by seeing such an obligation as part of the physician's non-delegable duty to ensure informed consent is obtained, even if this obtaining is carried out vicariously.¹³⁶ *Who* gives the information to the patient is seen by Slovenko¹³⁷ as *the crucial factor* in determining the voluntariness of consent, and he suggests that other "health professionals" should "dilute" the relationship with, and information given by, the patient's own physician.

There is a further comment to be made here and this is that the duty to inform the patient is not fulfilled once and for all, but is a continuing one throughout the procedure¹³⁸ and even possibly after it is complete, as patients should be warned if adverse reactions become apparent later. Perhaps the most important application of this continuing duty is if new parameters of risk are discovered after consent was obtained but before the procedure is completed. This is especially true if such a development occurs during a controlled trial, as this adds to the problem of deciding when it becomes unethical to continue such a trial. The additional modification required in such circumstances is that it would certainly be unethical to do so without further disclosure and consent.

Finally I would like to briefly mention some corrective mechanisms and safeguards which may be worth using to enhance the protection afforded by the doctrine of "informed" consent.

Firstly, as a legal mechanism, one can insist that the patient is not able to waive the right to be informed, at least in a non-therapeutic situation. Then, with respect to imposing legal liability on a doctor for non-disclosure a lenient test of causality should be accepted,¹³⁹ such that the failure to disclose need not relate directly to the injury which eventuated. In this respect the approach of the Civil Law, as outlined by Giesen, seems a desirable one. He says that "[s]elon les jurisprudences française et allemande, prouver un lien de causalité entre l'intervention pratiquée sans le consentement éclairé du malade et le préjudice causé suffit à établir la responsabilité du médecin. Contrairement à la pratique juridique suivie en Grande-Bretagne, les tribunaux ne cherchent pas à savoir si le malade, à supposer qu'il ait été convenablement informé, aurait ou

non refusé de donner son consentement''.¹⁴⁰ The adoption of such an approach would lighten the burden of the patient in proving causation and really means that liability is imposed for loss of a chance to refuse to participate in treatment, an opportunity which would have existed if the required disclosure had been made.¹⁴¹

Lombard *et al*¹⁴² compare the effect in French and American Law of a failure of the doctor to inform the patient. In French law, he says, this amounts to "dol"—fraud—which means the contract is "nul" due to a failure of consent. However, failing to inform the patient is not actionable *per se*, but only if the doctor is at fault in making a decision which has untoward consequences, when he is liable for damages caused by this fault, which is aggravated by the fact that he took the decision alone.¹⁴³ In comparison, in the United States of America, if the doctor does not properly inform the patient, he is liable for all resulting complications even those caused without fault.¹⁴⁴

Less legal corrective mechanisms and safeguards for consent, but ones which may enter into proof of the validity of the informing, are a two part consent form,¹⁴⁵ in which the first part gives the information and the second part is a questionnaire subsequently administered to test the degree of comprehension. This is especially important in medical research where only those subjects displaying a sufficient level of understanding may then participate as subjects.

Again in relation to medical research, Hershey and Miller, and Gray, suggest methods which are not directly related to assessing the understanding of the required information by any particular subject, in order to test the validity of the informing. Hershey and Miller¹⁴⁶ believe that a certain percentage of refusals should be anticipated if the risk is properly explained and that the researcher should be required to keep a record of these refusals. Gray¹⁴⁷ suggests one should examine the decision factors considered by the persons who agree to become subjects, in order to assess the validity of their consent, to the extent that this depends on the information given and understood. If, for example, it is an objectively risky study and no subject reports considering risk, or if there is no benefit to the subjects but no reasons of altruism are given, then there is at least evidence that the subjects have not been informed, or have not comprehended the minimally required amount of information for "informed" consent.

Any such review of consent should obviously be carried out by a disinterested party and, in fact, this shows another safeguard applicable here, which is peer or committee review of the validity of the consent. At one stage this was even specifically provided for in some D.H.E.W. Regulations,¹⁴⁸ which established special "consent committees" as well as general review boards which also had a duty to determine the validity of the consent given by research subjects.

Rather than just reviewing the consent given, it would also be possible to require participation of an independent third party or parties in the consent process, even including a review committee itself where this was otherwise involved in the situation "to make the consent decision more genuine".¹⁴⁹ In relation to medical treatment carrying any significant risk this is probably the most practical and worthwhile safeguard and such a third party could be a relative of the patient, or someone of his choosing, or a nurse, or medical social worker. As well as helping to ensure proper disclosure by the doctor and comprehension by the patient, such a procedure overcomes any criticism that the doctor rather than the patient made the decision to operate.

To summarize what I see to be a desirable approach to the informing of patients:

- (1) all material or relevant risks must be disclosed as well as other factors related to the treatment which could influence the patient's decision to participate, that is, the disclosure must be complete, accurate and not too complicated;¹⁵⁰
- (2) the test of materiality of information should be objective *vis à vis* a "reasonable patient", with the proviso that this test becomes subjective to the extent that the physician knew, or ought to have known, that additional information which would not have been relevant to the "reasonable patient" was in fact material to this particular patient or subject in his decision-making;
- (3) the test of required comprehension of the disclosure should be "apparent subjective", that is the doctor must take reasonable steps in relation to the particular patient to ensure that he understood and that objectively, or apparently, he did;
- (4) care should be taken that the informing process is not coercive, and possibly in some circumstances an estimation should be made by a "disinterested" outside party in this respect and with respect to the effectiveness of the informing process;
- (5) in non-therapeutic experimentation there can be no mitigation of these standards and no waiver of the right to be informed is allowed;

- (6) in the therapeutic situation waiver, “therapeutic privilege”, and a duty not to inform, may all apply depending on the circumstances, but generally there should be a presumption that they are inapplicable, with the burden of proof to the contrary on the person alleging this, and with the rebuttal of the presumption only being upheld when the circumstances clearly indicate it.

2. The duty to inform the patient of his medical record or of experimental results

The other matter which I wish to deal with here, is also a duty to inform the patient, but in contrast with the duty to obtain “informed” consent, is more in the nature of an *ex post facto*, or performance of the contract duty, rather than a formation of the agreement or “consensus” obtaining obligation. This may be described as the right of the patient to his medical records or to the results of any experiment carried out on him, and a corresponding duty to inform the patient when he chooses to exercise this right, or when it would be detrimental to him not to be informed.¹⁵¹ The duty is framed in this way because an overriding duty to disclose may be detrimental to the patient. For example, some authors think it is unethical to inform a person of an untreatable prognosis,¹⁵² which I submit is an acceptable approach to the extent that the person does not seek the information.

In many jurisdictions there has been debate¹⁵³ regarding the right of a patient to his own medical records, and whatever the decision reached in the normal therapeutic situation, I propose that at least all experimental subjects must be given this right, whether the experimentation was therapeutic or non-therapeutic. There may be some difficulties with such a right. For example the French *Code de la Santé publique*¹⁵⁴ states that a patient may not be told “la nature des produits essayés, les essais eux-mêmes et leurs résultats.” In the United States of America the F.D.A. had relied on their argued exemption from the disclosure requirements of the *Freedom of Information Act*¹⁵⁵ to withhold all drug trial results, although the basis for this practice was upset by a court decision¹⁵⁶ holding such information to be generally disclosable pursuant to the Act.¹⁵⁷

It is a separate question whether restrictions on disclosure would be, or should be, applied against a patient, or a research subject who helped generate results as opposed to an “outsider” who seeks the same information. One difference is that in the latter case problems

of consent and questions of privacy and confidentiality may be involved. There are also other reasons which may require disclosure of research results to a patient or subject where this would not be required in relation to a non-subject. For instance, the subject's participation may be regarded as identifying him with the research and earning him some "quasi-proprietary" interest in the results, at least to the extent that he needs these for his own health care. While dealing with this topic, it is worth mentioning that the fact that a person participated in research should be entered on his medical record and, possibly, should be recorded in some central data bank as a means of protecting "ex-subjects" of research from risk.

Another way in which a distinction may be made with respect to the rights of subjects and non-subjects to research results, is by differentiating between rights and duties. For instance the *Freedom of Information Act*^{157a} in the United States deals with *rights* to disclosure, but it says nothing of an independent *duty* of the researcher to disclose the results to the patient.

I submit that, except where a doctrine of "therapeutic privilege" would apply, a patient should have at least a right to examine his medical file if he so desires. Further, the subject of an experiment should have a right to know the experimental results related to his participation. For such a subject this right is a corollary to that of confidentiality, as the latter means he has a right *not* to have such results disclosed, except to the extent that he consents to this. If it can be anticipated that having knowledge of his medical record, or experimental results, may harm a patient or research subject, the situation can sometimes be dealt with by a prior agreement that the information need not be disclosed, except where it would harm the patient not to disclose it. Such non-disclosure could always be legally challenged and the burden would then be on the physician, as it is in "therapeutic privilege", to prove that the withholding of information was justified. A legislative example of such a scheme is found in the *Loi sur les services de santé et les services sociaux*¹⁵⁸ of Quebec. This provides that a person

to whom an establishment refuses access to his record or refuses to give written or verbal communication of it may, on summary motion, apply to a judge of the Superior Court, Provincial Court, Court of Sessions or Social Welfare Court or to the Commission, to obtain access to or communication of it, as the case may be.

The judge shall order establishment (sic) to give such . . . [person] access to his record, or communication of it, as the case may be, unless he is of opinion that it would be seriously prejudicial to the health of such . . . [person] to examine his record.¹⁵⁹

It may be that in certain circumstances this suggested duty of *ex post facto* disclosure is even more intense, for example when a randomized controlled trial, either double or single blind, has been carried out and the patient has consented to a certain amount of initial non-disclosure. In such cases there may be a duty to inform the participants after the trial has finished of what they actually took or had done to them, again with a restrictively applied exception that this is not necessary where such disclosure may harm the patient. This is a difficult matter to assess here, as some persons may be psychologically upset on learning, for example, that they exhibited profound side-effects when taking lactose tablets.

B. OBTAINING CONSENT OF THE PATIENT OR RESEARCH SUBJECT

1. What is the purpose of consent?

It has been emphasized that one must look at the principles underlying rules which have evolved to regulate the medical relationship, and enunciate the purpose these rules are designed to achieve if one is to judge whether the rules are necessary, or effective, or whether some better system can be evolved. Nowhere is such an approach more needed than in the elucidation of the nature of consent, and in the controversial area of the necessity or otherwise of obtaining it, and in determining what minimum quality of consent suffices as at least the legally, if not ethically, acceptable entity.

What is the purpose of requiring consent? This would appear to be a simple question which is often answered by saying that it is to protect the autonomy and integrity of the individual. But the numerous responses given in the literature are much more subtle in their distinctions than this straightforward, but not very instructive, reply as to how or when the aim is achieved, and some responses may even constitute a departure from this answer. Certainly it is an enlightening exercise to examine some of the opinions and reasons given for requiring consent. Not the least of these is that in dealing with patients unable to consent, one cannot dispense with or substitute for the usual requirement of consent unless one knows why consent is required in the "normal" case. Only then can one tell whether this purpose can be achieved in other ways.

Firstly there seem to be some presumptions underlying the requirement of consent. Gustafson¹⁶⁰ describes these as a moral assumption that a person has a right to determine his own destiny and a philosophical judgement that he is capable of doing so. In the context of medical experimentation, these presumptions are expressed by Beecher¹⁶¹ as a belief that the researcher has no right to choose martyrs and that society will not tolerate the domination of subjects by researchers, and that it is the function of the "myth" of "informed" consent, to ensure that this is not occurring.

The presumptions underlying consent are given more specific content by Brody,¹⁶² who says that consent used to be seen as necessary in order to establish a patient's interest in a procedure, and that its ability to do this depended on a presumption that the person would act in his own self-interest and for his therapeutic benefit, that is self-protectively. However there has been a change from consent being seen as only promoting this interest in self-protection to its function also including protection of an interest in self-determination.¹⁶³ This change eliminates the need for the presumption of self-protection as, if a truly free and informed consent is obtained, whether the results of the procedure to which consent has been given are good or bad for the person in the sense of helping or harming his physical or mental integrity, there is no doubt that at least in his original decision he is being self-determinative. With such a change other presumptions are introduced which relate to the assumption that it is possible to obtain adequate consent and that the right to self-determination is an overriding good, which is to restate and support Gustafson's conclusions referred to above.

In contrast to the presumptions underlying consent there are also some important presumptions as to the nature of consent itself. Jonas,¹⁶⁴ for instance, describes consent as not being a permission but a willing, and Crépeau explains consent as a matter of judgment and will.¹⁶⁵ These statements imply the necessity for some positive element in the concept and purpose of consent, rather than seeing its function simply as a neutralizing of liability which would otherwise be present. In this respect it is interesting to look at the old Common Law pleading of consent which reaches back to Bracton,¹⁶⁶ and which was by way of the term "leave and licence".¹⁶⁷ The defence of consent had to be raised under the general issue, not as a matter of special pleading, which meant it was *not* regarded as a "justification" to be pleaded by the defendant by way of "confession and avoidance",¹⁶⁸ but rather as an allegation that if consent of the plaintiff were present, then the necessary and sufficient elements of a

cause of action in assault or battery for instance, were absent.^{168a} I suggest that these words “leave and licence” have a much stronger connotation than a mere waiver of legal rights by the plaintiff, as a waiver effect would be more consistent with regarding consent as a justification. Rather they import a notion of positiveness, of intention and willing by the plaintiff with respect to the act perpetrated by the defendant so that the defendant, relying on consent as a defence, admits the act but avoids a cause of action. Thus liability is avoided by the defendant’s proving the positive right given to him by the plaintiff to carry out that act.¹⁶⁹

This leads to, and is consistent with, the purpose which some authors see in consent of transferring power. Paquin¹⁷⁰ says the doctor only has the power given to him by the patient and for this reason needs consent. Annas and Glantz¹⁷¹ say that consent has been developed to give the patient more power and to equalize the doctor-patient relationship. It is obvious that these authors are starting from opposite presumptions: the former that the patient has the power, which is usually legally and morally true,¹⁷² and the latter that the doctor has the power, which is often more factually realistic.

Shannon¹⁷³ also sees the role of “informed” consent as related to power, but as part of a more complex structure. He argues that medical researchers, for example, need a wider loyalty or value base than purely self-interest or scientific interest¹⁷⁴ and that therefore they must view membership of a profession as “a way of integrating the [professional] individual and society”¹⁷⁵ and of “specifying social obligations and responsibilities”¹⁷⁶ for them. These two factors together will force the professional “to perceive the research subject as a fellow citizen”,¹⁷⁷ which will *weaken the power of the professional over the subject*. This is the same function that “informed” consent plays in the structure. It does this by informing the researcher that he cannot just do what he wishes, and helps the subject to learn that he has rights which must be respected.¹⁷⁸

Other writers also state that the purpose of consent is to maximize respect for the person,¹⁷⁹ or more specifically to ensure that the patient’s interests are considered and respected,¹⁸⁰ or promoted.¹⁸¹ At the least, such respect requires involving the patient in decision-making which affects him, and may even demand that society’s views in this regard are taken into account as well. Consent is one method of promoting this respect for the person, either by setting rules as to what is recognized as a valid consent by an individual or, with respect to direct societal control in the decision-

making, by specifying acts to which one may or may not consent. Recognition that respect for the person must be ensured, whether as a function of consent or in other ways, is essential to recognizing persons as being of moral worth¹⁸² or, in negative terms, to avoid “tampering with human beings, getting at them, shaping them against their will¹⁸³ [which] . . . is . . . a denial of that in man which makes them men and their values ultimate”.¹⁸⁴

How effective consent is in achieving this aim will depend to some extent on the degree to which consent is seen as having *only* a symbolic function of maintaining respect for the individual. In relation to medical research, where respect for the person is most important and often most threatened, Freund¹⁸⁵ has argued the worth of the symbolic function of consent. He notes that by symbolizing respect for the individual it forces the researcher to rethink and articulate the experiment in these terms, and has “a valuable reflexive effect on the enterprise itself”.¹⁸⁶ That is, apart from raising sensitivity to the subject’s rights, consent may promote a medical purpose by having a salutary effect on the actual medical techniques and procedures used. Such a symbolic effect is good, but it is more disturbing to see the defence lawyers in the *Kaimowitz Case*¹⁸⁷ arguing that consent is not necessary because it serves *only* a symbolic function¹⁸⁸—a different content of meaning and effect than that foreseen by Freund.

In another group of purposes attributed to consent, one finds Calabresi¹⁸⁹ seeing it function as the minimum requirement in striking a balance between present individual lives and future lives in general, and as reducing the directness of the decision to use the former to benefit the latter. This is in accord with his general theory¹⁹⁰ that there is conflict between society’s role as protector of the individual, and society’s role in deciding when to sacrifice the individual for the common good. Calabresi believes the decision in the latter case must be made indirectly in order to preserve the appearance of the first “protector” role of society, but that the decision, when made, must reflect society’s values. Thus to the extent that society allows an individual to consent to medical interventions, by not characterizing such a decision as contrary to “public policy” or “public order and good morals”, it allows the individual “via” the mechanism of consent to implement its own latent policy decisions.

Childress,¹⁹¹ in a related argument, and speaking of medical research, sees consent as decreasing the sacrificiality otherwise

involved in this activity.¹⁹² This somewhat negatively phrased purpose of consent can be compared with the positive ones of only suffering chosen risks,¹⁹³ or of generally protecting the patient.¹⁹⁴ Within this latter purpose some authors advocate that consent should be seen as a guideline to help the patient reach total well-being, and not be seen as a goal in itself.¹⁹⁵ The aim here is probably to emphasize that consent is usually a necessary, but not a sufficient condition for ensuring the legitimacy of an intervention.

There is yet another more philosophical and sociological purpose foreseen in consent. Traced in opinions of commentators from various disciplines, this purpose may be termed that of identification. First of all there is identification of a patient as a person. May¹⁹⁶ says that personhood is a gift each confers on others and that one therefore becomes a person with the help of other members of the community. The consent situation is definitely an inter-personal encounter,¹⁹⁷ the problem being that it may be de-personalized¹⁹⁸ and with this the involved patient may be de-personalized as well. This may be done deliberately, or subconsciously, by a medical researcher, for example, as a self-defence mechanism.¹⁹⁹

Jonas²⁰⁰ also speaks of identification, not so much in the sense of seeing the subject as a person, but rather of the strength of that person's connection with the purpose of the proposed intervention. This can be related to the former type of identification because the more strongly the person identifies with the purpose of the research, the more he is participating as a person in contrast to being used as an object. This he sees as the basic principle allowing, or prohibiting, the choice and use of a human subject in medical experimentation. Such identification is achieved, I suggest, by means of the subject's informed and understanding consent to participate in research, research with which he is sufficiently objectively identified.

This same idea of the purpose of consent, that is to identify the patient or subject first as a person and then with the treatment or research undertaken on him, is probably Ramsay's intent when he speaks of consent as showing fidelity,²⁰¹ and as demonstrating a common bond between the patient or subject and the physician or researcher, making experimentation for example, a joint venture, a partnership.²⁰² Further, Parsons²⁰³ describes the same concept in sociological terms when he says consent is a two-way process: of the professional complex to "admit" the research subject to, and of the

subject to accept the status of, membership in the associational collectivity.

Possibly Gray²⁰⁴ had such an identification-participation idea of consent to medical research in mind when he wrote that the failure to obtain “informed” consent deprives the research subject of an experience, threatens the integrity of the research project as it then becomes inhumane, and is a violation of ethics poisoning the general atmosphere.

A further purpose for obtaining consent may be to achieve certain legal effects connected with, but distinguishable from the fact that, as a matter of law, it may be necessary to have consent. The concept of consent is related to the concept of responsibility and those who consent must bear the consequences of their decision, that is, one function of consent is to shift responsibility and with it liability.²⁰⁵ It may be, as Edsall²⁰⁶ argues, that “informed” consent is too easy a hurdle for the medical researcher to clear, especially if legally it has this effect of fully shifting liability. Further, the presence of consent should be inconsistent with that of coercion or duress, concepts which have both factual and legal content. While this is clearly the aim in obtaining consent, care needs to be taken that consent is not a cover for coercion or duress, rather than guaranteeing their absence.

Apart from any disadvantages there may be legal advantages for the patient arising from the fact that consent is required. It may be easier to prove lack of consent than to prove negligence,²⁰⁷ or to prove the elements of a cause of action based on the former rather than the latter;²⁰⁸ further, the impossibility of obtaining consent may be used as a total bar by a court,²⁰⁹ or legislature,²¹⁰ to prohibit certain practices.

Within the context of examining the legal purposes related to consent, one should note specifically that consent does not justify medical experimentation or euthanasia, for example. Justification of research on humans, for instance, depends on the inter-relation of multiple factors. The legal effect of consent, in contrast to some extent to the legally implicated purposes which it may serve, is to make conduct potentially defensible which would be actionable without it.²¹¹ However, consent does not act as a sole justification of such conduct. Rather, once adequate consent is shown, justification will depend on other factors outside the realm of consent. In my opinion, the distinction between consent as a sufficient and a

necessary condition is important to keep in mind if consent is to serve its protective function and not be left open to abuse, especially as a cover for practices which would not be justified on the basis of criteria other than consent.

Such a cover role for consent can be seen in some statements of the reasons envisaged as underlying requirements for obtaining consent. The American Heart Association, for example, seems to regard the purpose of consent as being primarily to protect the doctor from legal liability, when the Association regretfully recognizes that it “does not afford absolute protection to the physician”.²¹² Similarly, when Wolfensberger²¹³ speaks of consent as being a “release for the researcher”, he is seeing its function as being protective of the researcher rather than of the subject. Clearly consent is protective of the doctor or researcher in the sense that normally he is legally and ethically at fault in failing to obtain it. But to describe it in this way is to warp the purpose the concept is designed to promote. It would be the same as my saying that it is protective of myself not to murder people because to do so would subject me to legal liability, and therefore the reason for the law prohibiting murder is to protect me.

I would advocate a strong emphasis on the purpose of consent as being protective of the patient. This may require an express statement as to whether the protection of his rights to autonomy and inviolability are absolute or relative, and in the latter case the terms of this relativity. There should also be strong emphasis on the idea that consent is usually necessary, but not sufficient, to ensure legal and ethical validity. I would also promote a view of consent as a guideline which is *always* applicable, even if the goal is only sometimes, or never, attained.²¹⁴

2. Should consent be defined?

There is one major reason why consent should not be defined, at least in terms of the procedures necessary to attain it, and this is because normally when one has complied with the definition, then legally the defined entity is deemed to exist. It would be possible to legislate a very stringent definition of consent but it is bad policy to enact unattainable legal standards. Rather than raising the level of adherence the effect may be a total disregard of the law.²¹⁵

The United States D.H.E.W. Regulations give a general definition of "informed consent": "the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion".²¹⁶ This provision must be seen as outlining the characteristics of "informed" consent and not as implying that if the procedures mandated in the Regulations are followed, such consent is deemed to be achieved. An express statement to this effect is included in other Regulations specifically applicable to mentally disabled subjects: "Nothing in this subpart [which outlines additional procedural protection for such patients when they participate in medical research] shall be construed as indicating that compliance with the procedures set forth herein will necessarily result in a legally effective consent under applicable State or local law to a subject's participation in such an activity."²¹⁷ This is to argue that the procedures required by the Regulations are only safeguards attempting to ensure that "informed" consent is obtained and are not definitive as to what fulfills this.

There is a problem in this interpretation however, as the same Regulations require the "Review Board", the ethical review committee, to certify that "*legally* effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of this part";²¹⁸ and the institution where the research is conducted is "obligated to obtain and document *legally* effective informed consent".²¹⁹ If following the specified procedures is not conclusive evidence that "informed" consent is obtained, then as the Human Experimentation Subcommittee of the Research Board of the University of Toronto pointed out to the D.H.E.W., "in Canada 'legal effectiveness' could only be determined after the fact by litigation".²²⁰ An arrangement was therefore negotiated by this University with the D.H.E.W. whereby the certification made was that, "in so far as the review committee could determine, the informed consent was unlikely to be legally ineffective".²²¹ Perhaps as the D.H.E.W. accepted this, it represents the sense in which the Regulations are intended.

Another reason not to define consent, except as characteristics which are apparent when it is present, is that it must be seen as a continuing requirement, not something which is achieved once and for all when a subject agrees to participate in an experiment. Further, definition of consent may tend to detract from the notion of continuing change in content of the consent, which is also inherent in

this concept. Seeing consent as a continuing process correlates with the continuing duty to inform which has already been discussed²²² and emphasizes the notion that the patient is *free to stop consenting*, which is usually described as freedom to withdraw from the treatment. I suggest that this latter phraseology undesirably implies that a positive act of discontinuance is necessary on the patient's part, rather than seeing consent as the positive act, in the absence of which there is a return to a neutral or usually presumed position at any time.²²³ This same distinction can be seen in the terminology used to describe why consent is needed. One can say the patient consents to treatment, or consents to waive a right against treatment. There is more emphasis in the second description on the need for continuing consent, as the right is only waived while the consent continues, whereas in the former there is more an impression of having given consent to a particular treatment once and for all, and that subsequent withdrawal depends on a separate right of revocation. The overall result is the same, but the underlying attitudes are not necessarily the same.

One of the difficulties in seeing consent as an on-going process involving the continued participation of all parties,²²⁴ may be caused by legal doctrine on the concept of consent within the areas of obligations, torts, and contract. Especially within the contractual framework, with its requirement of *consensus ad idem*, consent is assessed when and where the "meeting of the minds" of the parties occurs. Now the medical relationship in all jurisdictions is almost always²²⁵ at least partly contractual, and this gives the impression that consent is given once and for all at the time of entering the contract. The problem can be overcome by envisaging that there are *two consents* involved: consent to the contract and consent to the medical care given under the contract; and that the duty to obtain the latter, and the continuing obligation to do so, arises under the contract.²²⁶

The reason that such a distinction may be important, apart from promoting the idea of the necessity for a continuing consent, is that it liberates this consent to the procedures undertaken on one's person from any restricting contractual doctrines. For example, in Common Law, whether or not there is *consensus ad idem*, that is consent giving rise to a contract, is judged objectively.²²⁷ This may be an unethical standard to apply in assessing consent to a medical intervention. By separating the two consents involved, one can then envisage the contractual consent, if it is present, within its normal context and as governed by the usual rules. Then one can regard the

consent to treatment as a right and duty created by the contract or by law, and in either case as not limited by or dependant on the rules of formation of contract, but as founded rather on rights given under the contract or by law, or even on basic human rights,²²⁸ any of which may be much broader.

Also one can argue that the distinction between “consent” and “‘informed’ consent” is observed in this division of consent to the contract and consent to the treatment, respectively. Prosser,²²⁹ speaking of the intentional torts such as trespass to the person, for instance assault and battery which are among the most ancient of the Common Law actions, says the consent which was necessary to negate the wrong, was to the defendant’s conduct not to its consequences. Such torts were prosecuted under specific writs and it was “via” the development of a more general writ, “an action for trespass on the case”, and under this, allegation of an assumed obligation, *assumpsit*, and subsequent breach, that contract and its consensual doctrine developed.²³⁰ Thus, in the history of the Common Law, tortiously and contractually relevant consent were related. Possibly the former, being more ancient, influenced the latter, and as the tortious rule was that the consent need only have been to the conduct of the defendant actor to be taken into consideration as negating the actionability of his act, this may show the need to develop a “consent as to consequences” requirement—“informed” consent—which may also be founded in tort, or alternatively, on a contractual obligation basis. The advantage of such bifurcation with respect to both the two consents and the two juridical regimes applicable, is to emphasize all the different necessary elements and effects of consent, and would tend to overcome assumptions such as Toole’s,²³¹ that there is *no assault* in prescribing a drug and therefore, he concludes, *consent is not necessary* in undertaking this procedure. It is true that assault and battery does not lie here because any damage caused is indirect and unintentional and therefore it is irrelevant to consider the necessity of consent in the intentional tort context. But to conclude that this means consent is not necessary, that is that consent is only relevant to avoid commission of assault or battery, shows the absolute necessity of adopting the dual analysis suggested.

3. Is consent possible?

In outlining characteristics of “informed” consent and suggesting some guidelines and safeguards towards ensuring that it is

obtained, one assumes that it is possible to attain this goal, a supposition which is far from undisputed.²³² Beecher named the doctrine the “myth” of “informed” consent²³³ and warned that one must recognize the problems inherent in it if it is to be used properly. The principle of requiring “informed” consent is correct, he says, the difficulty is achieving it. He concludes that the reality envisaged can only be approached and almost never fully attained.²³⁴ Portes²³⁵ is of the same view: “le consentement ‘éclairé’ du malade . . . n’est en fait qu’une notion mythique . . .”. He suggests that “nous donnons au mot de consentement sa signification habituelle d’acquiescement averti, raisonné, lucide et libre”.²³⁶ Similarly Pellegrino²³⁷ believes consent is never wholly free or wholly informed in an absolute sense and therefore he advocates a change of nomenclature to “valid consent”. Ingelfinger,²³⁸ on the other hand, describes consent as “informed but uneducated”, meaning to indicate by this that there is neither adequate understanding, nor total freedom of choice.²³⁹ Vidal and Carlotti²⁴⁰ also see free and clear consent to treatment as impossible, but regard it as non-essential in protecting the patient. This is because they view a therapeutic aim as the sole justification for a medical intervention, not consent, and the free and clear consent which they argue is needed and is protective is that relating to choice of a doctor, not the treatment he gives.²⁴¹

Some of the views expressed above pre-date the trend towards more emphasis on “informed” consent in all jurisdictions, but, to the extent that they still apply, the danger that they represent is that in saying that “informed” consent is impossible to obtain, a reaction is engendered that therefore there is no obligation to try to obtain it. Such an obligation is denied by the use of a principle rather like the old Equitable maxim that “Equity will not order the impossible”.²⁴² For this reason, I suggest, the desirable attitude is to regard “informed” consent as a process rather than an event, in the sense of both needing continued informing and consenting, and of trying to achieve the desired aim. One may visualize consent as a continuum, with the minimum requirement in order to justify a medical intervention on a person depending on a relationship of relevant variables, but on which the aim should be to come as close to the ideal as possible. This moves the discussion to the next consideration: “is consent always necessary?” For, at one end of this proposed continuum, there may be a point at which the intervention is justified without any “informed” consent being present.

4. Is consent always necessary?

Although this question has been canvassed to some extent within the discussion of rights against treatment and the doctrines of autonomy and inviolability,²⁴³ it merits separate consideration with the slightly different emphasis that is given by approaching it from the viewpoint of the necessity of consent.

There is a distinction made by McCormick²⁴⁴ which is worth noting here, as it serves as a useful analytical tool. This is the difference between the ethics *of consent*—that is when consent is required—and ethics *in consent*—how the requirement is applied and fulfilled. These are closely related, partly because the ethics applicable to each category depend on the same variables. Hence the discussion so far, which has principally concerned ethics *in consent*, is also relevant to what follows, where the problem focused upon is the ethics *of consent*.

It seems that one can formulate a general rule that consent is always required to a medical intervention on the person, but that some codes, courts and commentators recognize exceptions to this general rule, though the bases and extensions of these exceptions vary.

Firstly, in the therapeutic situation there may be two such exceptions, one of which may be regarded as apparent and not real, since consent is presumed. This occurs in an emergency when the patient is factually unable to consent, and consent may be implied. The very fact that such an implication is made supports an assumption that consent is necessary.²⁴⁵ Whatever the basis used to justify such an emergency intervention, it is not usually a cause of legal problems in any of the jurisdictions, unless there have been untoward results. Liability in such cases is judged according to ordinary malpractice standards, which may be even less stringent than usual in view of the emergency circumstances in which the doctor acted. The more difficult decision arises when consent is expressly refused by the patient. The question is whether a doctor is justified in overriding this, that is whether consent may be regarded as unnecessary and its refusal may be ignored. In Civil Law jurisdictions the answer to this question in situations posing a serious threat to a person's life or health is more clearly, but not absolutely, yes,²⁴⁶ than it is in similar circumstances in Common Law²⁴⁷ jurisdictions.

When one moves into the area of medical experimentation the exceptions to needing consent are narrower and apply, if at all, only in therapeutic experimentation. Such an exception is most clearly applicable when the experiment is the patient's last and only chance to avoid serious morbidity or death, so that the nature of the situation more closely resembles the normal therapeutic one described above. In this situation the same rules as for therapy including exceptions to needing consent, arguably apply.²⁴⁸

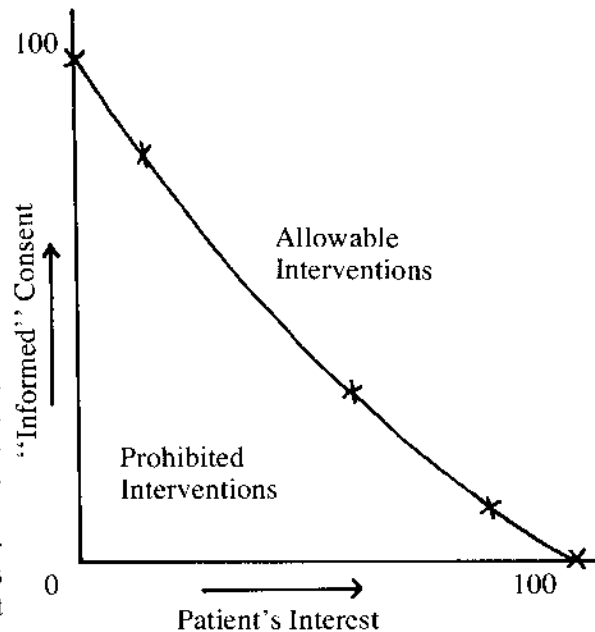
In non-therapeutic medical experimentation some authors say consent is always necessary and others argue for some exceptions. This apparent conflict only arises in a peripheral area where the experimentation does not require any contact with the patient/subject, for example in a retrospective survey using clinical notes, or when it can be argued that the research involves *no* risk (if this is possible since by definition there are always unknown risks in research). However, one can make an undisputed statement about a central core of non-therapeutic research: that in non-therapeutic research this consent is *always* necessary.²⁴⁹ The exceptions to needing consent which are argued, include large population studies²⁵⁰ and the use of medical information already obtained about identified individual patients,²⁵¹ or of clinical results.²⁵² It is debatable whether some of these examples are research on the person²⁵³ and that consent may not be needed for this reason. But to argue that one does not need consent to "no-risk" experimentation,²⁵⁴ especially where this is non-therapeutic, or to minor procedures,²⁵⁵ or that "modification" of the consent procedure may be allowed if there is, *inter alia* "minimal risk",²⁵⁶ is another matter and misses the point of consent. Consent is required not just to ensure that a person is not subjected to "roles", including that of a research subject, without freely choosing them, but also to ensure that respect for him as a person is maintained. This means that he cannot be used for any purpose without being informed of, and consenting to, this purpose, whether or not the procedure involves risk.²⁵⁷

Fried²⁵⁸ makes a very interesting comment, which is worth considering in relation to whether consent is always necessary in the contexts of both therapeutic and non-therapeutic research. He proposes that one may override a person's express wishes in order to *protect* a third person or the public, and he argues compulsory vaccination is an example of this, but that one cannot compel a person to confer a *benefit* on others. Thus, depending upon where one draws the line between what is protective and what is beneficial, arguably some non-consensual, non-therapeutic experimentation

could be legitimated. One of the difficulties with this distinction is that as protection is a benefit, it may largely be a matter of semantics whether a particular situation is characterized as either protective or beneficial. However the example selected by Fried gives a key to a more restrictive interpretation of his statement. This is that the vaccination procedure envisaged, as well as being protective of the community, is at least of potential and prophylactic benefit to the subject and is therefore not “pure” non-therapeutic research which by definition is *only* for the benefit of *others*. Thus, I submit that *to the extent* that any research procedure is *only* for this latter purpose, whether the aim is designated as protection or benefit, it cannot be compelled. This statement must be made, however, subject to the proviso that the situation *may* be different where the proposed research subject himself threatens the health of the community^{258a} and the research intervention is the least harmful or restrictive alternative available to deal with this threat.

Within the context of exceptions to needing consent to medical experimentation one may consider the situation of “non-subjects” of research, participants from whom consent is never directly sought. These are the persons subjected to television advertising of “over-the-counter” (O.T.C.) or non-prescription drugs, or they may be the “innocent by-stander” suffering effects from research carried out on someone else—for example exposure to radio-activity from a nuclear powered pacemaker inserted for their spouse’s heart. There is increasing awareness of the ethical and legal duties owed to these people²⁵⁹ and it may be that in the future they will have a greater right to be informed, even if their consent is presumed from their subsequent participation in a certain activity.

In conclusion one can summarize the main points about whether consent is always necessary, in the form of a graph, which is for the purpose of general description rather than mathematical exactitude. When the procedure is crucial to the patient's well-being, then the stringency and scope of the criteria for fulfilling the requirement of "informed" consent decrease accordingly. Towards one extreme consent may be either pre-



sumed or regarded as unnecessary, such as in an emergency situation involving an unconscious patient. But at the other extreme, if there is no therapeutic interest of the patient being promoted by the procedure then in order to ensure that his interests are protected, fully "informed" consent must be obtained. If this is impossible then because the procedure may not be carried out without consent, the experiment cannot be conducted. In the intermediate situations whether or not a doctor is justified in going ahead at a certain balance of less than fully "informed" consent and less than purely therapeutic interest of the patient is a matter to be judged individually according to *all* the circumstances of each case. It should be kept in mind, that if the patient is unable to fully comprehend, the doctor has an ethical and probably legal duty to decide whether to give or withhold treatment²⁶⁰ and that this duty cannot be "passed off" by an uncomprehending consent or refusal. In other words the doctor has a duty in relation to consent, which obliges him to tread the fine line between disclosure and non-disclosure, and at the same time he has duties other than that relating to obtaining consent; the former duty may be in conflict with the latter. There is a narrow median path by which all duties will be honoured, which must be re-drawn for each fact situation.

5. Is consent sufficient?

This question has already been indirectly canvassed under the purposes of consent²⁶¹ and, at a more empirical level, is related to prescribing scientific prerequisites and requirements for the validity of a treatment or of an experiment. The answer is that neither in ethics nor law, is consent a sufficient justification for a medical intervention therapeutic or non-therapeutic, experimental or routine, though it is necessary. This insufficiency can be described in terms of requiring conditions precedent to consent, which may be the scientific validity of a proposed treatment or experiment, or the therapeutic aim,²⁶² or, that the treatment is justified,²⁶³ or, in non-therapeutic experimentation it might be the superior interest of a third party.²⁶⁴

As well as needing such positive conditions to be fulfilled before a doctor may be justified in obtaining consent, there may be a duty not to obtain consent, that is when certain conditions are present, this duty arguably arises. This is probably the negative expression of needing certain conditions precedent to justify obtaining consent, but formulated in terms of a negative duty it is a more forceful statement. Wing,²⁶⁵ for example, says it is unethical to seek consent to a trial of psychiatric therapy which will harm the patient; Hamburger,²⁶⁶ speaking of transplant donors, expresses the same idea when he says the doctor has a duty to assess if the decision to donate is reasonable; Cahn²⁶⁷ says if one argues that the patient can consent to anything, then the doctor is morally bound not to accept certain consents; Capron²⁶⁸ maintains that the doctor cannot accept a patient's consent to unreasonable risks;²⁶⁹ and Shannon²⁷⁰ notes that one element of "informed" consent is prudence, which means that even if "informed" consent is given it cannot be just mechanically accepted.

This leads to discussion of the valid "extent of consent", a phrase that can be used in two ways. One reads that the doctor is limited by the extent of the patient's consent, that is he cannot act outside the area delimited by that consent except in circumstances when he would be justified in acting without consent at all. In other words the patient does not consent to any intervention the doctor chooses but to interventions within certain limits, and beyond these there is no consent.²⁷¹ Generally the cases involved here are discussing interventions which went beyond the physical bounds or nature of the intervention to which the patient consented, as opposed to interventions which were within these limits but were performed in a manner to which consent was not given. It is probably only if the

consent were conditional on some particular method not being used, or the method was experimental and there was no express consent to this characteristic, that the methodology alone would take the intervention beyond the extent of the consent. There is in other words a presumption that the content of a patient's consent is impliedly only to standard treatment, anything outside this requiring express delineation to be included in the consent.

The other use and meaning of the phrase 'extent of consent', seeks to mark out how far a patient can validly consent to an intervention. This is the area of 'public policy' and 'public order and good morals'. Firstly, all jurisdictions are consistent in holding that a person cannot validly consent, in the sense of exonerating the actor from criminal liability, to an intervention which would amount to a criminal act regardless of consent.²⁷² Decocq²⁷³ explains the ineffectiveness of consent here in a most persuasive way. He says it is not the consent which is inoperative but the implicit authorization of the law which is missing. Depending on whether one regards a particular legal system as 'closed' or 'open' respectively, this observation can be phrased in this way, or, alternatively, that an implicit prohibition of law is present.²⁷⁴ Nizsalovszky,²⁷⁵ speaking of Hungarian law, expresses a similar limitation, when he says that consent is limited to an intervention which is socially justified, that is that does not impair society. More philosophically than legally, Lynch²⁷⁶ writes that one cannot consent to bodily mutilation, as one does not have rights to this extent over one's body.²⁷⁷ In the same vein, Cahn applies such a principle directly to the problem of the limits of consent in human experimentation, and concludes that '[e]ven a free consent must have moral limits in a society that honors human dignity, and honoring it, puts a ceiling price on truth'.²⁷⁸

6. Must consent be in any particular form?

The answer in law generally is in the negative, unless a particular form is expressly required. Such a requirement is attached to some types of medical procedures in some jurisdictions. Lombard *et al*²⁷⁹ comment that in France consent forms are not in common use, as they are in the United States of America. In the latter jurisdiction such forms are not required under Common Law, unless one argues that their use is customary practice for a 'reasonable' doctor and that therefore this practice is incorporated by way of the case-law on 'informed' consent as a necessary element of the standard of medical practice required by law. This, I submit, is most unlikely.

An example of express provisions as to the form of consent may be found in the D.H.E.W. Regulations, which apply only to medical research funded by that body. These require documentation of "informed" consent and the details governing this documentation are spelt out at some length. Alternatives are given of full written consent, a witnessed oral presentation plus a written "short form", or some approved modification of either of these in certain specified circumstances.²⁸⁰

In Quebec written consent is required for hospital care, with separate forms for treatment involving an anaesthetic or surgery²⁸¹, and Article 20 of the *Civil Code of the Province of Quebec* requires consent to organ donation or experimentation to be in writing. This provision has been the subject of some academic comment and the better view is probably that the writing required here is a substantive, not a procedural requirement, and that therefore the consent is non-existent legally until expressed in writing.²⁸²

With regard to consent to experimentation on cadavers, all of the jurisdictions discussed have anatomy and autopsy statutes and have proposed or actual legislation on cadaver organ donation which would cover experimental use of tissues²⁸³, and which provide for consent formalities by the person themselves before death or statutorily nominated persons after death, or even imply consent in the absence of provision to the contrary.

There is arguably some danger in requiring formalities, such as writing, with respect to consent. Firstly form, when established, often has a tendency to replace substance. However, provided that the requirement of writing and even the use of a "pro forma consent form", is seen as less of a device for informing and more as an adjunct to this, and at best seen as rebuttable evidence of consent, the benefit of additionally using the written form outweighs the risks. The other dangers of requiring written consent relate to revocation. These may be partly avoided by making a very clear distinction between the formalities required for giving and revoking consent. In the latter case, if it is considered desirable to require formalities such as writing, these should only be regarded as evidentiary and not constitutive of legal rights and duties. Revocation of consent is therefore immediately effective in whatever way it is expressed.²⁸⁴ A danger of requiring written consent which cannot be easily set aside is that the formality itself may act as a coercive influence on the patient or research subject not to change his mind, or to withdraw at a later time.

C. VOLUNTARINESS OR DEFECTS OF CONSENT OF THE PATIENT OR RESEARCH SUBJECT

It is not enough to obtain the consent of the patient. The consent decision must be voluntary, that is, the act of a person who is "so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion".²⁸⁵ Gray describes this same requirement of voluntariness in another, and probably even more perceptive and instructive way, when he says that it means that the person must be free to refuse to participate,²⁸⁶ and Cahn labels lack of this freedom the "major malpractice of our era, [which is] 'engineering consent'".²⁸⁷

The words used to describe the situations in which consent lacks the required voluntariness are part of common vocabulary but also have technical legal meanings,²⁸⁸ and within the area of consent to medical interventions, these legal concepts collectively must be taken to cover the widest area possible within their terms. One way in which such an extension could be supported is by comparison between the quality of consent needed to fulfill the consent requirement in the formation of a contract, and that needed for obtaining "informed" consent,²⁸⁹ the latter being subject to much more demanding standards. Similarly, but inversely, I submit that the lack of voluntariness which will vitiate "informed" consent is of a much lesser degree than that which will constitute a defect in consent to a contract.

In regard to the burden of proof of consent, in Common Law jurisdictions where a relationship is characterized as confidential, or fiduciary, undue influence is presumed to be present.²⁹⁰ This means that in the medical contract the doctor has the burden of proving the voluntariness of the consent, which burden should be regarded as encompassing both the consent to the contract and consent to the medical procedure that it contemplates.

The same result with respect to burden of proof of consent is probably attained, but more indirectly, in Civil Law. For example in Quebec, Mayrand says "que l'exécution de l'obligation du médecin [here to obtain free and clear consent] étant un fait conforme 'à l'état normal et habituel des choses' la charge d'établir le fait anormal, c'est-à-dire l'inexécution, incombe toujours à celui qui l'allègue" but "la preuve de l'inexécution d'une obligation étant la preuve d'un fait négatif . . . elle se fait très simplement par le témoignage du

demandeur. Le malade ayant affirmé que le médecin ne lui a pas donné l'information requise, il appartient ensuite au médecin de contredire cette preuve.²⁹¹ In France the situation in this regard has been interesting. From 1936 to 1951 the courts held the doctor had the burden of proving that the patient's consent was free and clear,²⁹² then the *Cour de Cassation*²⁹³ stated that the burden of proving inexecution of the contractual obligation to obtain consent lay with the person alleging this, the patient.²⁹⁴

There is much technical, legal discussion on the effect of defects of consent on the consent itself, which it is impossible to canvass here,²⁹⁵ but this effect can be summarized as two alternatives: either the defect is so serious that it totally negates the presence of consent, that is the consent is null or void *ab initio*, or the defect may make the consent subject to rescission or voidable. The further question then asked is whether the absence of consent affects the nature of the allegedly wrongful act; that is whether presence or absence of consent, in some circumstances, is determinative of lawfulness and unlawfulness, respectively, or whether consent is merely a justification for an otherwise unlawful act.²⁹⁶ Whichever view one takes in answer to either of these two questions, this legal discussion may be distinguished or side-stepped as it relates to consent in the formation of contract, or consent in the areas of tort, or delict, or succession, or consent for criminal law purposes, and may not necessarily be directly applicable here. If one regards the obligation of the physician to obtain consent as one of performance of a contract, then this is breached by failing to obtain adequate and effective consent, and the result is a complete absence of the necessary consent as required by the terms of the contract for which damages may be sought. There is then no need to bring forward all this other complicated legal doctrine unless some remedy or sanction in one of these other areas is desired, when the obligation to obtain consent will not be characterized as contractual, but will be cast in another "role".

With regard to the factual determination of when consent is not voluntary, or alternatively when force, fraud, coercion, duress, undue influence, deceit, constraint, mistake or deception are present, the potential situations are unlimited and each case must be determined individually in the light of all the circumstances. One can, however, give examples, which are applicable generally in the form of analogy and cautions. The most pertinent of these cautions is that these coercive factors may be at their most subtle and difficult to detect, and freedom of choice most threatened, in a situation in which

the more powerful party believes he is acting for the benefit of the other.

1. Coercion and duress

Gray²⁹⁷ gives some examples of subtle pressures to participate, which were disclosed in interviews with subjects of therapeutic experimentation—a labour induction study on women giving birth. He found that the women consented because they feared damage to their relationship with the doctor,²⁹⁸ that they lacked knowledge of the options open to them, and that the consent of the patient to use of the experimental, labour-inducing drug had not been sought in a *neutral* situation—it was sought after admission to the hospital and after agreement to induction of labour, that is after patients had already committed themselves to undergoing the induction treatment by some technique. It is almost as though the consent were being obtained in increments so that the width of the decision lost its psychological impact. This raises the consideration that perhaps the patient involved in medical research should be considered a “special subject” along with prisoners, the mentally retarded and other “disabled” or “disadvantaged” persons,²⁹⁹ as some authors believe that he is the most likely of all to suffer coercion.³⁰⁰

It is also possible that this coercion does not just arise from the doctor-patient relationship but may be caused by a patient's fear of pain and discomfort, or fear that if he refuses a treatment or does not participate in suggested research, he will receive less attention generally.³⁰¹ Exactly where one crosses the line here from unavoidable intrinsic influences on consent, to legally operative extrinsic coercion, is difficult to determine. Bloom outlines three attempts to analyze the nature of coercive pressures on patients. Firstly he quotes Caudill,³⁰² who found that fellow patients in a mental hospital exerted pressures on new patients to co-operate with the doctors. Goffmann,³⁰³ on the other hand, argues that a power structure is the origin of coercion in the hospital situation. He says the staff-inmate split creates a power differential which causes the patient to “play the game” to avoid punishment. The third theory is that of social re-motivations—that patients adopt the attitude or value system of the staff towards their illness and treatment.³⁰⁴ Whichever of these is true, all show coercive forces acting on patients, as far as consenting to submit to medical treatment or research, and underline the necessity of taking special care to protect patients in this respect. Recognition of such coercive phenomenon probably explains the

reasoning behind what, at first reading, appears to be a somewhat unusual situation in the United Kingdom, where safeguards for healthy volunteers are not so strict as for patients. For example, there is usually review committee approval before carrying out experiments on patients, whereas this is not the practice with research involving normal volunteers.³⁰⁵

I wish to note here a rare, but thought-provoking situation, with respect to deciding when consent is coerced. "Thomas" was an aggressive psychopath, who may have been helped by experimental psychosurgery. Small electrodes were implanted in his brain and when these were stimulated he was "normal", at least with respect to his psychopathic tendencies. At such times he consented to psychosurgery, but adamantly refused when his brain was unstimulated.³⁰⁶ Should one argue here that Thomas was coerced into "normality" and therefore his consent was invalid?

There are other examples of coercion involving patients. The doctor might make it a condition precedent to treating the patient at all, that he participate for instance in an experiment³⁰⁷, or collateral benefits, such as the waiver of hospital fees, might be promised in return for such participation.³⁰⁸ This, in effect, is a form of payment and raises the whole question of payment as a form of coercion.³⁰⁹ As Lord Harley said in *Vernon v. Bethell*:³¹⁰ "Necessitous men are not, truly speaking, free men, but, to answer a present exigency, will submit to any terms that the crafty may impose upon them." This statement summarizes the coercive aspect of payment, but this is not the only objection to its use, especially in the medical research situation. Many authors argue it epitomizes the "reification", the dehumanization,³¹¹ the use, rather than the participation, of the subject in research. Payment may be regarded as emphasizing the fact that in human experimentation, "[t]he experimental subject does not hazard his physical capacities by using them. Rather, by abstracting his purposes from those in which his body is risked, he makes his body into a separate thing which he sells or gives away so that others may pursue *their* purposes with it".³¹²

The law's attitude to monetary payment "vis-à-vis" one's body varies in different jurisdictions. The general view in French law is that the body is not able to be an object of sale,³¹³ and although these statements are often made in the context of the sale of organs or tissue for transplantation, one assumes that the same prohibition applies to medical experimentation on the person where this is otherwise allowed. The matter is not entirely straightforward however, because

some French writers argue that payment in the nature of compensation or indemnity is permitted,³¹⁴ and in Common Law jurisdictions, where payment for participating in experimentation is not prohibited *per se*,³¹⁵ writers propose that it should be regarded as compensatory in order to avoid a coercive effect.³¹⁶ The net result in each legal system with respect to placing “benefits” in the hands of research subjects would thus be the same, although one starts with diametrically opposed general rules on the validity of payment.

In Quebec, Mayrand³¹⁷ notes that as in France, the human body cannot be an article of commerce, and also that one can distinguish recompense from commercialization. He says it is not clear whether Article 20 of the *Civil Code of the Province of Quebec*, forbids payment for experimentation,³¹⁸ as it certainly does in regard to alienation of non-regenerative tissue. This prohibition could, of course, be directly relevant to some experimental situations. Crépeau³¹⁹ proposes a distinction between “sale” and “letting of services” and suggests payment for experimentation may be valid under the latter, although he queries the validity of a policy which makes a distinction allowing payment for experimentation, but not for non-regenerative organ donation.

Where payment to experimental subjects is legally allowed, or more precisely is not prohibited, various suggestions have been made to avoid the coercive effects of such a practice, which are at their strongest where deprived subjects are involved.³²⁰ Cahn³²¹ says that payment is valid as long as it does not purchase an unwilling consent, which probably means one must determine if there would not be consent without the payment. In this case the apparent voluntariness may be due to the payment, which would therefore be coercive and destructive of the legal validity of the consent. This type of reasoning however leads to a difficulty. One always has reasons for consenting, and these reasons cause one to make a certain decision. It seems that once these reasons are identified they are to be divided into two categories, coercive and non-coercive, although, in the broadest sense, they are all coercive of the decision reached. Thus the criterion for marking-off the boundary between the coercive and non-coercive groups is not a difference in kind between such factors, but a matter of degree, that is some deviation from the normal pressures under which people find themselves. Daube describes such normal pressures as those influences which are “part of the normal burden and dignity of social existence”.³²² This is a useful description for identifying coercion because it requires, in order to designate a factor as non-coercive, that persons be in a “normal” situation and allows

one to recognize that the fact that they are not is itself coercive, and may cause other factors normally coercive, to become so.

One may see Freedman's³²³ approach to coercion within this framework: his view is that a reward to bring a person up to a standard of living to which he has a right is duress, but a reward above this level is not; that is, he says, it is the *effect* of the payment, the payment not *per se*, which is determinative of coercion. It is true that one is only interested in the coercive force represented by payment, that is with characterizing its effect in this respect, but the problem is that it is here that one has the most difficulty in drawing the line between allowable and prohibited pressure. For instance taking Freedman's criterion of coercion, quite apart from any questions of whether this is broad enough, what is a "normal" economic position of a person? Certainly if one, or one's family, is starving, to offer payment for experimental participation is coercive, but what if one is just poor, or earns less than the average, or wants more than most other people? Perhaps the answer may be that to be consistent with a principle of autonomy, one must judge the situation objectively and determine whether the coercive pressure of the payment arises from extrinsic need, in which case it is duress, or from intrinsic desires, in which case it probably is not.

In relation to payment of medical research subjects there is a further anticoercion recommendation made by Hershey and Miller³²⁴ that payment be made *pro rata* over the participation period, which has the additional and necessary safeguard effect of ensuring that a subject is not coerced into continuing with an experiment just because payment is an all-or-nothing, "lump-sum" event, at the end. In this respect it is interesting to note that the D.H.E.W. Regulations, applicable to research on prisoners, appear to be even more stringent. They provide that "withdrawal from [a] project for medical reasons [must] not result in loss of anticipated remuneration"³²⁵ which implies that the subject receives full payment for "part performance" in such circumstances.

The Report of the Committee to Investigate Medical Experiments on Staff Volunteers,³²⁶ referred to above, makes the interesting comment that payment of staff volunteers is desirable for "establishing the voluntary character of the service", that is for demonstrating that it is not an expected obligation of employment, which would be a coercive belief. Thus one has covered the full range from payment being fully and solely coercive to its being needed to rebut coercion³²⁷ and the only general rule which can be formulated with

respect to identifying coercion, is that each situation must be judged according to its own circumstances.

That being said, it is however possible to formulate some safeguards which may be applied to reduce the likelihood of coercion generally, including when this is in the form of payment. The first step is to increase sensitivity to, and recognition of, possible coercive influences. The sources of interference with the power of choice can be drawn together and categorized under these headings: the content of the required disclosure; the relationship of the physician, or others, to the patient; the setting for obtaining "informed" consent and the time; the language used; the inducements or compensation in the medical research context. All of these points have already been discussed.

Then consideration should be given to whether consent should be obtained by an independent third party and not the physician, or whether, in some circumstances where "informed" consent is particularly suspect, an ethical review committee should participate in the consent obtaining process by patient interview before the committee. It should be noted in this respect that Annas, Glantz and Katz are of the opinion, that "'third person' participation in the consent process is grossly inferior to complete [review committee] participation".³²⁸ In the medical research context a further protection against coercion is solicitation by general notice rather than by direct approach, or in such a way that initiative to participate is left with the volunteer.³²⁹ The final and ultimate safeguard against duress is to ban the activity in the promotion of which it is likely to occur, or to prohibit participation in such specified activities by any group of particularly susceptible individuals.³³⁰

A more subtle approach is to set stringent conditions, which will tend to ensure that coercion is avoided, a "no, unless . . ." type of regulation. In other words research is prohibited unless certain conditions precedent, chosen for their ability to reduce or eliminate the likelihood of coercion being concurrently present, are fulfilled. Such an approach has been recommended for general application to research involving prisoners in the United States of America.³³¹ As Hershey and Miller say: "It is virtually impossible to determine directly whether a decision is based on a 'free power of choice'. Thus, it must be defined by the absence of unacceptable influences and interferences, which is the approach that the D.H.E.W. regulations take."³³²

2. Mistake and deception

Two possible sources of error affecting consent are first mistake and secondly deception or misrepresentation. The two concepts are not necessarily exclusive, as the latter encompasses the former, and although treated separately by the Common Law, fall under one broad category of error in Civil Law. It is useful however, for the sake of analysis, to distinguish two situations: mistake—where the error is not induced intentionally, nor usually as a direct result of the words or conduct of the party against whom mistake is alleged as a defect of consent; and misrepresentation—where the wrongful belief is induced by the party not in error, either innocently, negligently, or fraudulently. It is important for legal purposes to distinguish these latter categories, as the remedies available will differ according to which is applicable. However, in a broader sense they are all instances of deception, even though in a legal context this word is sometimes used only as a synonym for deliberate concealment or fraud. In the medical context, the word deception may carry the inference that the misrepresentation was intentional and made by the physician for a particular type of purpose, that is to promote some interest other than, or even in addition to the patient's.³³³ Further, depending on the circumstances a non-disclosure or concealment may fall within either mistake or misrepresentation, but with respect to a doctor's non-disclosure of information he is under a duty to disclose, it will be the latter.

Firstly, it is necessary to consider the effect of mistake on both the consents relevant to the medical situation, that is consent to the medical contract and consent to medical care.

Mistake, like other defects of consent, may vitiate consent to a contract, including a medical contract. At Common Law, the rules on when mistake has the effect of nullifying consent, and hence the contract to which it was given, are among the most highly technical doctrines to be found in this system.³³⁴ The presence of mistake is, in general, assessed objectively.³³⁵ Whether or not it is operative to void consent going to the formation of a contract, which is the only legal effect mistake may have at Common Law,³³⁶ may depend upon whether the mistake is characterized as unilateral, common or mutual, that is the mistake is only on the part of one party, or the same mistake is shared by both parties, or each party is acting subject to a different mistake respectively.³³⁷

In comparison, in Civil Law, mistake or error is a wider doctrine³³⁸ and is judged subjectively. But as in the Common Law,

the Civil Law doctrine determining whether or not consent to a contract is vitiated, either through relative or absolute nullity, that is whether the contract is valid, voidable, or void, is complicated. In summary, the determination depends on the concurrent application of two tests: first whether on the one hand the defect of consent is an obstacle to formation of the contract, that is to a *consensus ad idem*, or whether on the other hand there is a "consensus" but it is defective; and secondly whether nullity of the contract would sanction a rule in the public or private interest. In the former cases, respectively, the nullity is absolute, that is the contract is void. In the latter it is relative, that is the contract is voidable and this latter sanction can only be invoked by the person in whose favour such nullity is established.³³⁹

Without exploring these doctrines in detail, their significance here is that, at Common or Civil Law a patient whose consent to a medical contract was tainted by mistake, could seek to escape the contract. However, by itself, this remedy, even if available, is often only of theoretical significance to an injured patient.

With respect to the effect of mistake by the physician in relation to consent to the medical contract, it is both unlikely that he would be the party in error in regard to the nature or object of the contract, or that he could rely on the patient's mistake to argue that the contract was void³⁴⁰ or voidable. Therefore his mistake is of little practical relevance within the context of the current discussion.

Mistake affecting the patient's consent to medical care is more significant. The standard I have suggested is that the doctor may rely on the patient's consent as being valid, from the point of view of being informed, when there is "apparent subjective understanding" by the patient of the information required to be disclosed to obtain an "informed" consent.³⁴¹ If one applies this standard then the patient's mistake will be irrelevant unless a reasonable doctor would have known, or this doctor in fact knew, that the patient was mistaken. Similarly, when the question is one about the presence of consent for the purpose of the torts of assault and battery, that is consent in its traditional sense as compared with "informed" consent, subjective mistake by the patient will not vitiate consent if, objectively, the patient appeared to be consenting.³⁴² It will only be vitiated if the consent was induced by fraud and the patient was mistaken as to the nature of the act to which consent was given, and not just as to its consequences.³⁴³

Where the doctor is the party in error in relation to obtaining the patient's consent to medical care, if for example he inaccurately describes the risks of a certain procedure, the question is one of negligence or malpractice in performance of his duty to disclose or, if the error is intentional, of deception or fraud. In all these cases whether the patient's consent to treatment was valid or not will depend on whether the doctor's mistake, regardless of how or why it occurred, was such as to make the consent "uninformed" or even no consent at all.

To turn now to the more troublesome source of error in relation to obtaining "informed" consent, namely the use of deception³⁴⁴ in medicine generally, and in human medical experimentation in particular. Deception raises difficult problems at both legal and ethical levels. In practice the problem is probably discussed most frequently in the context of randomized controlled trials or psychological experimentation.

It is sometimes said however that the most common form of deception in medicine is when medical students represent themselves as qualified doctors or imply that the physical examination they wish to carry out includes some element of patient benefit when this is not the case. Such deception is of course inexcusable and any consent given in these circumstances would be legally defective.

Another example of deception reported in a medical journal³⁴⁵ which falls outside the area of medical experimentation also raises pertinent questions. A study was carried out on terminally ill patients in which an audiogram was done while they were alive, and after death if they were subject to a post-mortem autopsy³⁴⁶ the anatomical structure of the ears was compared with the audiogram results. The patients "of course"³⁴⁷ were not told the object of the research, but because there was a worry that they would be frightened by being selected if they realized that all selected patients died soon afterwards, therefore the researchers selected at random non-terminally ill patients as well and conducted audiograms on them.³⁴⁸ How one views such experiments depends on the position one takes with respect to deception. There are basically three possible positions: that deception is never justified; that it is only justified if there is consent to not being informed and the general nature of the withheld information is disclosed; or that it is justified according to various other conditions in certain circumstances.

The legal problems associated with deception involve firstly its effect on “informed” consent. When “knowing consent”³⁴⁹ is defined to include certain basic elements of information, can one consent to not being informed of these and still say that there is “informed” consent? Hershey and Miller³⁵⁰ say no, but some others are not quite as definite and would allow deception as apparently compatible with effective consent, within limits³⁵¹ which limits include disclosing that there has been concealment and obtaining consent to this.³⁵²

Apart from its effect on “informed” consent, deception may be either a tort, or delict, or even a crime in itself. As already stated, for private law purposes one can classify the misrepresentation which gives rise to the deception as fraudulent, negligent or innocent,³⁵³ and remedies that may arise include damages in tort or delict, or nullity of, or the right to rescind the contract if one purports to, or does exist respectively.³⁵⁴ It is also possible that a misrepresentation amounting to fraud, which requires an intent to deceive or at least a high degree of recklessness as to the truth or falsity of the statement, could be a criminal offence. Or it could be the basis of revocation of a licence to practice medicine on the ground that the fraud constituted unprofessional conduct.³⁵⁵

Ethically, deception is objectionable because it is an infringement of human dignity.³⁵⁶ The objections to the use of deception in any research, which objections may also be applied to medical research and even medicine more generally, have been summarized by Mead.³⁵⁷ They are: denigrating the subject, with the harm to him compounded by debriefing, as then he must somehow accommodate to the fact that he was deceived; causing the investigator to develop an attitude of contempt for other humans, which may cause insensitivity and delusions of grandeur;³⁵⁸ and a dual effect on science, in that the experimental results may not be entirely valid due to communication of multisensory subconscious clues as to the deception, with the result that the whole culture of experimentation becomes one in which human dignity is violated rather than respected.

If one is of the view that some deception is allowed, then what are the limiting conditions? In relation to medical research the Canada Council Consultative Group on Ethics³⁵⁹ attempts to answer exactly this question. The experimenter has the burden of showing the importance of the expected results and that no other methodology which excludes deception is possible. There must be no deception as

to facts which would affect a decision to participate, and the researcher must show that the deception will not result in harm to the subjects. Such harm includes adverse feelings to having been deceived. The subjects must be debriefed after the experiment and told of the reasons why deception was necessary. If such debriefing is impossible then deception cannot be used. I suggest one add to this, where it is possible, requirements of consent to being deceived³⁶⁰ and some prior disclosure of the general nature of the information concealed.³⁶¹ There must also be a requirement that the researcher make a full disclosure after the experiment and obtain the subject's consent to use the information generated, in default of which the information must be destroyed,³⁶² or given to the subject to use as he wishes. Such a provision makes it less likely that a researcher will conduct an experiment using deception where there is a strong chance of causing an angry reaction by subjects, as such subjects may then withhold consent to using the information. The latter alternative allows for the information to be preserved while still respecting, at least *ex post facto* and to some extent, the subject's right not to be used as a research subject without his consent.

It is worth pointing out here that where "informed" consent is not obtained prior to conducting a medical intervention, the patient's retrospectively operating acquiescence is not an "informed" consent but rather is in the nature of a waiver of any rights of litigation which he may have, or a ratification of the doctor's act. Such a situation may arise not only when deception has been practiced, and hence inadequate information disclosed. It may also arise when the patient is incapable of consent in an emergency situation, or suffering from temporary mental derangement, in which case a subsequent ratification of the treatment given is an alternative legal justification to the defences of necessity or implied consent.

To return to deception, it is possible to see it in an even wider context than that already described. When a relationship gives rise to express or implied expectations which are acknowledged as justified, that is, ratified by the party who must fulfill them, then to deliberately disappoint such expectations is a form of deceit. Fried calls this faithlessness.³⁶³ A physician may be guilty of faithlessness with respect to any type of obligation, including the general one of putting the interests of the patient first. If this occurs the physician can be said to be deceiving the patient in the broad sense defined. The same reasoning applies to the obligation to inform the patient and obtain valid consent, which is often the only obligation regarded as affected by deception. In a sense, in such cases, one has a double

deception, as one has deceived the patient in the wider sense by deceiving him in the more traditionally recognized context of deception, that is with respect to factual information. Rather than being superfluous, Fried's more general analysis and use of the term deception are particularly valuable in this area, as it gives insights in relation to the obligation to inform and shows that the aim must be to cut down, or eliminate, the faithlessness involved in any deception which takes place. This sounds like a contradiction in terms, but, under the full rigour of the conditions I have suggested, it may be that the doctor is not being faithless in deceiving his patient if he places the interests of the latter foremost. In fact, it is possible to view a justified use of the doctrine of "therapeutic privilege" as an example of precisely such a situation.

D. THE RELATIONSHIP OF "INFORMED" CONSENT AND PRIVACY

One can describe this relationship in two essentially reciprocal ways: consent acts to protect privacy,³⁶⁴ or privacy defines the negative and positive boundaries of consent. In other words privacy is invaded if the limits set by a consent are exceeded, and privacy may protect the right to participate in, or consent to, medical treatment or research.³⁶⁵ In either case the assumption is that one may not invade privacy without consent, but that consent negates any invasion of this pre-existing right. That is, privacy may be seen as a function of consent and therefore of autonomy.³⁶⁶ In the first description of privacy given above, the emphasis is more upon the determination of the extent to which the right to privacy is yielded by the consent given, and in the second, on the valid extent of the consent. But unless this difference in approach caused different presumptions to arise, there would be no variation in result in any specified case by using either of the concepts.

There is another relationship which needs to be spelled out here and that is between confidentiality and privacy and consent. Confidentiality may be described as an obligation arising in one person which is founded on another's right of privacy, which right has been suspended by consent to the limited extent of the confidentiality. Thus confidentiality protects rights of privacy by limiting further disclosure, whereas privacy and its consent requirement is the protection against initial disclosure. Ruebhausen and Brim³⁶⁷ make the distinction in this way: that consent concerns the

conditions under which information is obtained, whereas confidentiality concerns the conditions under which it is used. This is an instructive description, provided that one realizes that whether or not there has been a breach of confidentiality also depends on consent. Usually a patient does not, or should not, just give consent to the giving of the information. Rather, whether the information is given orally or by the act of participating in treatment, it should be consent to giving this information for a specified purpose.³⁶⁸

In the "pure" therapy situation the purpose for which information is given by the patient may be implied, that is to facilitate his treatment and cure. Any use beyond these limits, for instance using the information for research purposes, would need further express consent. Confidentiality, therefore, limits the use of the information to the purposes expressly or impliedly included within the consent and proscribes any other disclosure. A difference between confidentiality and privacy arises only if one regards an initial unauthorized disclosure as the sole breach of privacy, because something once revealed is no longer private in the strict sense of this term, and then considers further unconsented use or revelation of the same facts as breach of confidentiality. It is a semantic, rather than a real difference as regards both the content of the relevant legal or ethical obligation, and the overall outcome in terms of the ethical or legal validity of making a certain disclosure.

The purpose of a right to privacy is protection of the individual, his human dignity and right to self-determination, especially but not limited to, his psychological integrity, which has been called a right or claim to "private personality".³⁶⁹ The Canada Council Consultative Group on Ethics³⁷⁰ believe that a right to privacy provides for the deeply felt need of human beings to reveal to others only those aspects of their lives which they wish to reveal. This is a very significant aspect of human freedom and, as such, is often in conflict with society's search for knowledge.³⁷¹ More juridically and medically the French jurists³⁷² see the patient's "secret" as his extra-patrimonial property and the purpose of medical secrecy as preserving the integrity of the person, all of which assumes the existence of a right to privacy.

It is not possible, here, to show the history of the development of a legal right to privacy, which Berlin says derives from a conception of freedom only as old as the Renaissance.³⁷³ "[A]ncient law recognized that a person had a legal right 'to be let alone', so long as he was not interfering with the rights of other individuals or

the public. This idea has been carried into the common law, [which] . . . has both tacitly and expressly recognized the right of an individual to repose and privacy . . . ”³⁷⁴ There is wide recognition of the applicability of this right in the medical context, in the form of either a right to privacy or secrecy, or as a duty of confidentiality, which is more express in the Civil than Common Law.³⁷⁵ International documents founding such a general right are the International Covenant on Human Rights³⁷⁶ and, in the medical context, the Declaration of Geneva³⁷⁷ which specifically provides that the duty of secrecy survives the death of the patient.

British Columbia, in 1968, was the first Province to enact legislation protecting privacy³⁷⁸ followed by Manitoba in 1970.³⁷⁹ In Canada, *The Canadian Human Rights Act*³⁸⁰ legislates both a principle of “the privacy of individuals and their right of access to records containing personal information concerning them for any purpose . . . ”³⁸¹, and it enacts provisions applicable to the protection of personal information³⁸² in federal information banks.³⁸³ In an even broader context, Quebec’s *Charter of Human Rights and Freedoms*³⁸⁴ provides that “[e]very person has a right to respect for his private life”³⁸⁵ and “[a]ny unlawful interference with any right or freedom recognized by the Charter entitles the victim to obtain the cessation of such interference and compensation for the moral or material prejudice resulting therefrom”.³⁸⁶ Further, “in the case of unlawful and intentional interference, the tribunal may, in addition, condemn the person guilty of it to exemplary damages”.³⁸⁷ This last provision is especially interesting in relation to medical research, as, in many instances, breach of privacy in that context will be deliberate. With respect to showing that the act breaching privacy was “unlawful”, probably the Act itself by legislating a right to privacy creates this unlawfulness, at least as a *prima facie* presumption arising from a breach of privacy. Alternatively, unlawfulness may be based on a breach of the *Code of Medical Ethics* of the Professional Corporation of Physicians of Quebec,³⁸⁸ which has the status of subordinate legislation, and promulgates a duty of confidentiality.³⁸⁹

In the United States, Amendments to the Constitution have been interpreted by that country’s Supreme Court as conferring a right of privacy on all citizens³⁹⁰ and the American Medical Association Code³⁹¹ expressly recognizes a duty of confidentiality by doctors. Likewise the duty of confidentiality is recognized in the United Kingdom where both the British Medical Association³⁹² and the

British Medical Research Council³⁹³ state that there is an obligation on the doctor to maintain secrecy.

Remedies for invasion of this right to privacy, or breach of this duty of confidentiality may include an action for breach of contract. In Common Law jurisdictions, the remedies include the possibility of tort actions in defamation,³⁹⁴ or even perhaps for breach of confidence³⁹⁵ or of a right to privacy³⁹⁶ and, where there is a legislated duty of confidentiality, for breach of statutory duty.³⁹⁷ In Michigan breach of confidence by a doctor is a criminal offence.³⁹⁸ This can be compared with the situation in France where, as well as being an expressly legislated professional obligation,³⁹⁹ breach of confidentiality by a doctor is punishable under the *Code pénal* by fine or imprisonment.⁴⁰⁰

One must now consider exceptions⁴⁰¹ to this duty of secrecy. This raises firstly the relationship between privacy and confidentiality on the one hand, and privilege on the other. A doctor has a duty of confidentiality "vis à vis" his patient but this does not necessarily mean that he is privileged from disclosing the information subject to this duty, when ordered to do so by a court of law. The doctor, when he is required to testify, may claim to have a "medical privilege" which allows him to refuse to disclose his patient's secret, but in all jurisdictions there is some doubt as to the existence or extent of such a privilege, although it is recognized in Civil Law doctrine.⁴⁰² At Common Law the matter is less certain,⁴⁰³ but the same result is achieved by some courts through a holding that disclosure by a doctor of information gained in confidence from his patient is against public policy.⁴⁰⁴ Some jurisdictions have now legislated the privilege.⁴⁰⁵ The purpose of recognizing such a privilege is, as Portes⁴⁰⁶ said in a different context, that secrecy is essential for confidence and without confidence medicine is impossible.

It is necessary to point out here that the privilege involved is not the doctor's but the patient's⁴⁰⁷ and that therefore, it cannot be set up against the patient. The reason for belabouring this is that sometimes such a privilege is relied upon, in terms of rights of privacy of the doctor, to deny the patient access to his medical records. This I submit should not be allowed, except perhaps within the scope of a narrowly defined "therapeutic privilege".⁴⁰⁸ In other words the patient has two mutually consistent rights here, a right to privacy and confidentiality, and a right of access.⁴⁰⁹ Any conflict between them arises only when one considers third party access.

Where, in a case before a court, a doctor seeks to rely on privilege any denial of this by way of exception to the patient's right of privacy and the doctor's duty of confidentiality, is based on the state's power to administer justice and is not related to any theory concerning consent. Another such example of an exception to privacy not being related to consent, is when the respect for privacy may harm another⁴¹⁰ or perhaps even the person himself. In these instances one can argue that there should be a mitigation or suspension of the doctor's duty of confidentiality. One example of such a situation would be if venereal disease were diagnosed and the person's partner was unaware of this,⁴¹¹ or a disease were detected, and it is not in the patient's interest to be told this but others need to know of it in order to care for him.⁴¹²

The Medical Research Council of Great Britain⁴¹³ has dealt with the latter case, by providing that, unless *expressly forbidden* by the patient, the research physician should be willing to communicate information of which he gains knowledge to the clinician treating the patient when it is pertinent to the patient's health care. In some cases, such as notification of infectious disease, a duty to disclose is even legislated.⁴¹⁴ A more controversial disclosure without consent, is demonstrated in a United States case⁴¹⁵ where the court ruled that the public's right to be informed how its funds were disbursed, surpassed the privacy issue. The D.H.E.W. were ordered, under the *Freedom of Information Act*,⁴¹⁶ to disclose files on grants given by the National Institute of Mental Health for research on the use of stimulant drugs on children.

Other exceptions to the right of privacy and duty of confidentiality are related to consent, in that where consent is not considered necessary then privacy may be non-consensually invaded; or if consent may be implied then this occurs with only a presumed permission. An example of the former type of exception is that consent may not be needed to epidemiological research provided anonymity is maintained.⁴¹⁷ A possible instance of the latter exception is the generally recognized exception allowed for publication at scientific meetings⁴¹⁸ or in journals, provided, at least in the latter case, that the patient is anonymous and cannot be identified.⁴¹⁹ Express consent is not usually sought for publication.⁴²⁰ It is not clear whether this exception is based on implied consent as suggested, in which case publication could be expressly prohibited by the patient, or is a non-consensual exception to a right of privacy and duty of confidentiality, in which case it arguably could not be prevented by the patient, is not clear.⁴²¹

Special problems of privacy, particularly relevant in the medical research context, have arisen in recent years with the development of computers and information systems technology in general.⁴²² Since the "Ellsberg Affair" in the United States, one is particularly aware of the potential for harm that exists in the unauthorized use of psychiatric records. Such systems do not alter the doctor's duty of confidentiality, but may impose additional duties of records' security and care in order to prevent unconsented to link-ups or retrievals.⁴²³ The problems posed are not completely original, only more intense because of the increasing complexity and longevity of data collection and storage.⁴²⁴ Strict measures of control over access by the government or any person to computer stored medical information have been proposed in the United Kingdom,⁴²⁵ although evidently not implemented.⁴²⁶

Computer technology also causes additional problems in the medical context, apart from just those involved with preventing a breach of confidentiality. One of these is that if a breach occurs the data may not even be correct. For this reason Whalan⁴²⁷ has suggested that a new writ should be developed on the same principles as *habeas corpus*, which he has called *habeas notae*. It would compel production of a centralized record for inspection by the person concerned and allow for its correction. *The Canadian Human Rights Act*⁴²⁸ is pertinent in this respect, as it legislates a principle which embodies respect for "the privacy of individuals and their right of access to records containing personal information concerning them for any purpose including the purpose of ensuring accuracy and completeness . . . to the greatest extent consistent with the public interest".⁴²⁹ In relation to medical records, in particular, Quebec has legislated both a duty of confidentiality (with the exception that a "professional . . . may examine such records for study, teaching or research, with the permission of the director of professional services of the establishment which keeps such records . . .")⁴³⁰ and a right of access to them by the patient.⁴³¹

A discussion of information systems raises the consideration of duties regarding shared confidentiality or secrets. This is a problem discussed more often in Civil Law doctrine than in Common Law. Lombard *et al*⁴³² report that the Cour de Cassation has recognized a doctrine of *secret en commun*, and Boyer Chammard and Monzein⁴³³ note that the Conseil d'Etat regard medical secrets in group medicine as being confided to the group. Kornprobst and Delphin⁴³⁴ discuss a *secret partagé ou collectif*, the latter term being intended to overcome the objection that a secret is not a secret if it is shared. At

Common Law there is support for the belief that there may be a duty on persons supervised by physicians to observe the same degree of confidentiality as physicians,⁴³⁵ and Baldwin *et al*⁴³⁶ suggest that there is a notion of acquiescence by the patient to an "extended confidence", when he discloses to the doctor.

If this is true one must underline the word confidence and I suggest that as with other derogations from a patient's rights, one should place the burden of proof on the doctor to show that the course of action taken in sharing the patient's confidences was justified. In some situations, where it is clear that others will have access to medical information regarding patients, an extended duty of confidentiality has been legislated, binding on all such persons.⁴³⁷ Further, the recognition of an extended duty of confidentiality is particularly important where approval of a review committee is recommended, or obligatory, before a certain procedure may be carried out.⁴³⁸ Thus one line of attack against the mandating of such review requirements is that they represent an unjustified interference with the patient's right to privacy, in the sense of his being able to decide for himself and by himself what is done to his own body, and that they may interfere with the confidentiality inherent in the doctor-patient relationship.⁴³⁹

Other safeguards of privacy, even if not of confidentiality, may be developed if one sees this right as a function of autonomy and inviolability. That is, the right to privacy may be respected, although information is divulged, as long as one recognizes that that right requires the fulfillment of certain conditions precedent to disclosure. Those safeguards which have been or could be adopted include, as already suggested, the recognition that in situations where privacy is not to be protected by non-use of information, other adequate safeguards such as consent and anonymity, must be employed; that journals should only publish identifiable photographs with the signed permission of the patient;⁴⁴⁰ that medical records are regarded as the property of the patient;⁴⁴¹ and with respect to medical information systems, that the systems and the persons responsible for them are required to be licensed; that the persons using the information and the use to which it is put, be approved and recorded; and finally that adequate technical safeguards are required to ensure that information cannot be retrieved and misused.⁴⁴² Further, it is recommended that not only must consent to *collection* of patient data be obtained, but also consent to its *preservation*, as both threaten his privacy.⁴⁴³ Another recommendation is that there should be specific consent to the making of records and to the maximum period for which these

may be maintained before destruction.⁴⁴⁴ Finally it is worth noting that a safeguard of privacy which appears to be increasingly used in American jurisdictions in relation to medical research carried out in sensitive areas such as drug and alcohol abuse, is a legislated duty or privilege of confidentiality.⁴⁴⁵

The discussion, so far, has only considered a patient's right to privacy, but it has been suggested that a concept of privacy also applies to physician-researchers⁴⁴⁶ and more importantly, to ethical review committees. There may be a need for this in the latter case if the membership of a committee are to feel free to express their true opinions, but this advantage must be balanced against the need for openness and public accountability.⁴⁴⁷

In conclusion one wonders how far pragmatic analysis of the conflict of medical confidentiality and scientific research by Baldwin *et al*⁴⁴⁸ represents what should be the approach taken to these privacy problems. The reasons for transfer of medical information, they say, are clinical, administrative and scientific, and the question is not whether the information can be transferred for these purposes, but under what circumstances this should take place. This is a different starting point and hence results in a different emphasis and perhaps a different result, than does reasoning from a primary right of privacy and duty of confidentiality as the general rule, to which, as a matter of legal interpretation, exceptions are to be narrowly construed.

CHAPTER III

How are consent in the medical relationship, and the underlying principles of autonomy, inviolability and privacy affected by “disability” of the patient or research subject?

The first point to be made, is that the rights and duties expounded in the “normal” patient context apply equally to the group of persons whom I will call collectively “special patients”. And to the extent to which these rights and duties are unable to apply because of factual or legal disability or incapacity, that disability or incapacity must be regarded as a condition mandating greater protection of the person and not as justifying a derogation from rights which would be recognized with respect to “normal” persons. Consistent with this principle, an important general rule may be formulated in regard to medical research involving “special patients”. The rule is that it should be regarded as a condition precedent to involving any “special” patient in non-therapeutic medical research that the information required from the research cannot be obtained from other “normal”, that is competent, adult, non-institutionalized subjects.

Some of the matters already discussed do not need modification for application to a “special” patient, for example the fiduciary duty of the doctor. Or they are easily modified to accommodate the

interests of the "special" patient, for instance the juridical basis of the doctor-patient relationship. In the latter case, whether the patient is "normal" or "special", tort or delict duties of the doctor are equally applicable. With regard to establishing a medical contract, this is not different legally from setting up any other contract for an incompetent,⁴⁴⁹ in that account must be taken of both factual and legal incapacity of the patient and of the status of the person able to act on the incompetent's behalf.⁴⁵⁰

The major problem arises with regard to procuring "informed" consent, the "second" consent which as earlier proposed there is a duty to obtain in order to justify contravening the right to inviolability of the person.⁴⁵¹ The dilemma can be stated interrogatively: in what circumstances is apparent consent not consent because of the disability of the patient, and when can someone, other than the person himself validly allow another, the doctor for instance, to contravene an incompetent's right to inviolability? The answers whether in fact, in law or in ethics are not clear, but there are basic principles from which one can work out some answers.

Firstly it is important in formulating these principles that they be consistent with those derived for the "normal" patient. For example, I have stated that a major purpose of requiring "informed" consent is to fully extend the application of a principle of respect for the person.⁴⁵² With the competent patient this principle is honoured in both the concepts of autonomy and inviolability. But in the case of incompetent patients, because there is no autonomy, it requires a predominance of the inviolability concept, which means protection from harm and respect for his human dignity. This aim is not always easy to achieve even in the "pure" therapy situation and it is even more difficult to ensure when medical research on such persons is involved. This does not mean that it is impossible to carry out medical research on "special" patients, but rather that special care must be taken to ensure that such experimentation conforms to ethical and legal principles. This requires a close analysis of what is required in the "normal" situation, and whether and how these same principles can be honoured with the "special" patient, in default of which the research should be prohibited.

With this approach in mind I wish to examine the problems of consent in relation to the various categories of "special" patients, with an emphasis on the difficulties encountered in the medical research situation as this demonstrates most clearly the complex of issues involved.

A. CONSENT WITH RESPECT TO THE DYING, INCURABLE OR “DEAD” AS PATIENTS, OR SUBJECTS OF MEDICAL RESEARCH

One of the most difficult areas of consent is that with respect to euthanasia, which I will not deal with specifically here as the subject of euthanasia is being dealt with extensively in another paper in this series. Rather, I will consider consent in more general terms within a medical relationship in which the patient is dying or incurable. The conditions governing consent to euthanasia would be at least as stringent.

The possible coercive effects on consent arising from the dual role of patient and medical research subject have already been considered,⁴⁵³ but those who are dying or terminally ill may be considered a “special” sub-category. This categorization may alter the situation in two ways: first it may justify very risky therapeutic experimentation, if this is the only hope for the patient,⁴⁵⁴ and thus possibly widen the area of operation of the doctrine of “therapeutic privilege”; secondly, respect for the person as a dying human and the effect of dying on the ability to give “informed” consent,⁴⁵⁵ may restrict non-therapeutic experimentation which would otherwise be justified with “informed” consent on a non-dying subject. For these reasons the *Netherlands Report*⁴⁵⁶ disapproves of experimentation on the dying under any circumstances. Similarly, the *British Medical Journal*⁴⁵⁷ recommends that no experimental trials be conducted on the dying in the United Kingdom. Curran⁴⁵⁸ advocates that the F.D.A. regulations in the United States be interpreted as not allowing the use of dying subjects in drug trials, unless these hold out a hope of saving the person. As Beecher notes⁴⁵⁹ the inadequacy of classifying subjects as a special category entitled “dying”, is that because no time period is included everyone is arguably a present member of the class; and further it is unnecessary, unless it is meant to express detachment of the physician-patient bond. If the latter proposition were true, it would lead to the paradox that the healthier the patient the stronger the physician’s obligation to him and the sicker the patient the weaker the duty.

There is a matter which has been the subject of legislation and much academic comment which must be at least briefly touched upon here, and this is the determination of a dying patient’s death. The juridical and ethical regimes applicable to a dead person are based on different principles and have different aims than those relevant to the living person, and they seek to uphold respect for the dead person and

for the feelings of those by whom he was known and loved. After death such respect may not require inviolability, or this right's area of operation may be limited according to different criteria than those applicable to living persons, in that respect for the deceased, or respect for his relatives' sentiments, only requires that his wishes or theirs be obeyed.⁴⁶⁰ This is really to recognize an extended principle of autonomy, insofar as the will of the deceased or that of his relatives may be determinative, more than the principle of inviolability *per se*.

The problem which then arises is how to handle the situation where there is no overt threat to autonomy, that is in the absence of express wishes of the deceased or his relatives. In such cases there is a need for presumptions which will operate to determine whether organs may be taken or cadavers used for scientific, or therapeutic purposes. These presumptions are generally classified under two systems, that of "contracting-in",⁴⁶¹ where the presumption is that in the absence of the express consent of the deceased before death or of his relatives after death, the deceased's body is inviolable; or "contracting-out",⁴⁶² where the operative presumption is that all persons consent to the use of their bodies after death, in the absence of their or sometimes as well their relatives' express wishes to the contrary. In general these types of provisions, provided any required express or implied consent is present, are wide enough to allow medical experimentation on the cadaver, such experimentation being within the meaning for example of such provisions as "therapeutic purposes, medical education or scientific research".⁴⁶³

For the purpose of deciding which principles with respect to consent apply one must now determine when one is dealing with *inter vivos* medical experimentation and when with *post mortem*, which means determining death. As the subject will be dealt with in detail in another paper in this series, it is only necessary to give an outline of the problems involved in this determination here. One issue is that of whether or not a definition of death should be legislated.⁴⁶⁴ The difficulty is that death is a biological process, but the law requires an event, a precise point in time beyond which a person is regarded as dead. It is possible to mark this point anywhere along a continuum from permanent loss of the ability to interact with one's surroundings,⁴⁶⁵ to whole brain death, or even to cellular death at the other end. It seems that "brain death" is becoming more and more recognized as death of the person. But a further consideration is whether this criterion of death should be legislated, and, even if it is, whether it should be recognized as a sufficient criterion of death or

simply as one criterion, the determination of death depending, in any particular circumstances, on the clinical judgment of a doctor or doctors.

One should also be aware that there may be two points in time with legal significance here, and the distinction between them becomes more important if a concept of "brain death" is adopted. The first moment occurs when the doctor is justified in no longer taking extraordinary measures to keep the patient alive, or even perhaps, in discontinuing active treatment. This point will then subsequently be followed by the second, the moment of death. It is only when the person is already dead that it *appears* that the two moments, of withdrawal of artificial support measures and of death, coincide. Further, it is necessary to consider whether the fact that death is being declared for different purposes might call for different safeguards, including variations with respect to consent.⁴⁶⁶

B. CONSENT AND CHILDREN AS PATIENTS OR SUBJECTS OF MEDICAL RESEARCH

Here the problem is one of "informed" consent for reasons of legal, and when younger children are involved sometimes also factual, incapacity. Again this is a much debated topic, but some clear positions can be identified. One matter which can be settled immediately is that, in my view, the dangers of coercion associated with allowing payment for medical experimentation involving children, would never justify any advantages associated with this practice. Consequently, I propose that all payment in money or in kind should be prohibited except where it is genuinely an indemnity, or takes the form of a therapeutic advantage arising directly from the experiment itself.

1. Consent to therapy and therapeutic research

With respect to "pure" therapy or therapeutic research, which by definition is for the benefit of the child, the parent may give "informed" consent.⁴⁶⁷ This is so because the parent has both a legal right and duty to care for his child, in default of which, the state under its *parens patriae* power may intervene through its courts to order necessary treatment.⁴⁶⁸

On the same line of argument there seems to be no reason why a minor, who is able to consent to therapy, could not also consent to therapeutic research. The problem then becomes whether, and when, a minor's consent to therapy is effective. This is a much debated question, but one which has been resolved to a certain extent by legislation in some jurisdictions. For example, in Quebec a minor of fourteen years of age or older may consent to "care and treatment required by [his] state of health",⁴⁶⁹ as he may in at least one state of Australia.⁴⁷⁰ In Ontario,⁴⁷¹ British Columbia⁴⁷² and the United Kingdom⁴⁷³ he may so consent at sixteen years of age. The individual states, of the United States of America display a variety of legislation in this respect, which either generally lowers the age of consent to medical treatment, or does so at least for the purpose of obtaining consent to treat certain specified medical conditions.⁴⁷⁴

In default of legislation, or where there is legislation but a minor is below the age specified for consent, there may still be a problem about whether or not his consent to therapy is effective, except when the legislation *expressly prohibits* consent by a child below a specified age.⁴⁷⁵ One difficulty caused by some legislation is that although it does not prohibit consent below a certain age, it may create a presumption that it is meant to cover the field and hence abrogate any previous law and, when, interpreted strictly according to its terms, it may make a certain age of the child a condition precedent to his giving a valid consent. The United Kingdom legislation is noteworthy in this respect. It has a saving provision, that the Act does not make ineffective any consent which would otherwise be effective.⁴⁷⁶ I suggest that it is preferable to view all the relevant legislation in this way, except where this is impossible because of express statutory direction such as under the Quebec Act. That Act provides that the consent of the person exercising paternal authority is necessary when a minor less than fourteen years of age is involved.⁴⁷⁷

It is at least arguable that apart from, and except where abrogated by statute, at both Civil and Common Law a minor capable of discernment can consent to medical treatment. Here again it is important to make the distinction between consent to the medical contract and consent to medical care. I suggest, that even if the minor lacks capacity with respect to the former, he may have it in regard to the latter consent. This is particularly true if one argues that consent to a contract requires legal and factual capacity, whereas consent to medical care only requires factual capacity. Such an approach may even enable a minor to consent against the wishes of his parents.

Dierkens is of the view that: “les prescriptions du droit civil en matière de capacité régissent essentiellement . . . l’exercice de droits patrimoniaux. Elles ne sont pas d’application stricte lorsque les droits sur la vie ou le corps sont mis en question. La capacité naturelle, appréciée essentiellement en fonction du degré de maturité, peut prendre alors une importance déterminante. C’est ainsi qu’en cas d’absence ou même d’opposition du père, le mineur, qui jouit d’une maturité suffisante, peut, sans aucun doute, autoriser valablement le médecin à prendre les mesures conservatoires indispensables.”⁴⁷⁸ Similarly Crépeau,⁴⁷⁹ speaking of the law in Quebec prior to the enactment expressly requiring a minor to be at least fourteen years of age to consent to medical treatment,⁴⁸⁰ says that an adolescent minor capable of discernment had capacity to consent to a medical intervention and to enter a non-lesionary, that is therapeutically beneficial, medical contract.⁴⁸¹ This was so because “le droit à l’inviolabilité est un droit extrapatrimonial, personnel, qui ne saurait être exercé que par son titulaire s’il est en mesure de la faire et s’il est doué de discernement”.⁴⁸² This is still the applicable policy enshrined in the statutory provision allowing a minor to consent. The difference is that the criteria chosen for its application are a specified age and, presumably, discernment,⁴⁸³ rather than solely the latter.

In Common Law there is very early authority establishing that a minor can enter a medical contract. Coke⁴⁸⁴ states that “an infant may bind himself for his . . . necessary physic”, and an ancient case, *Dale v. Copping*,⁴⁸⁵ held that the necessities for which a minor can contract include medical services. One must realize here that the fact that the contract was for a “necessary” overcame invalidity of the contract even due to lack of consent, not just invalidity due to lack of capacity in the sense of legal status. Hence the minor could be bound to such a contract although incapable of discernment; the basis of his liability was either that being for a necessity the contract *must* have been entered in some way, therefore lack of actual consent was irrelevant or alternatively, consent establishing the existence of a contract may have been implied by legal fiction from the minor’s state of necessity. Whatever the basis for this law, its application is conditional on the medical contract being “necessary” for the minor.

Where the treatment is not within the above category but is for the benefit of the minor, there is support, including that of Nathan, for the view that if the minor has the intellectual capacity to fully appreciate the nature and consequences of the medical procedure performed for his benefit, then he can give a valid consent.⁴⁸⁶ On the other hand, one author sums up the situation at Common Law as

being “not clear if the minor has power to consent [or] whether one must also obtain the consent of the parent”.⁴⁸⁷

One must here again make the distinction between the two consents involved, that to the medical contract and that to medical care, in order to understand the authorities and aid analysis. Coke was speaking of consent to the medical contract,⁴⁸⁸ Nathan and the other authorities quoted,⁴⁸⁹ of consent to a medical intervention, in the sense of consent being necessary though not always sufficient, if an intervention is not to constitute a crime, nor the torts of assault or battery. The vital question with respect to minors is, whose consent in the latter sense is both necessary and sufficient?

In an interesting historical approach Annas, Glantz and Katz survey the early Common Law on minority and conclude that the concept of an age of majority was based on feudal law and custom, and is not related to modern needs.⁴⁹⁰ However, even within the limitations of this early law a study of Blackstone⁴⁹¹ shows that minors were not without significant legal capacity, for example with respect to marrying, or making a will disposing of their personal estate. Also, if one looks to minors’ consent in the law of torts in general, it is often assumed to be present in non-, or minimal, risk situations, as otherwise every physical social contact would become an assault and battery. Further, where risks are involved, if the minor understands these and voluntarily accepts them, his assumption of risk either for himself or of his conduct to others, is as valid as for an adult.⁴⁹²

The question then becomes should any general ability at law of a minor to consent to being touched, or to acceptance of risk, be modified in the medical context. The rationale for allowing the parent to consent for the child, putting aside any prerogative the parent may have arising from his liability for costs incurred as a result of successful or unsuccessful treatment of the child,⁴⁹³ is that the former is better able to take into account all the interest of the latter, because the latter is incapable of making an educated and rational choice.⁴⁹⁴ This argument applies in the case of a minor incapable of discernment, but not necessarily to a mature minor, and hence the “mature minor” exception to needing parental consent has been recognized by various courts. This rationale also explains two other generally recognized exceptions to needing parental consent to therapy on a minor. These are the emergency situation, where what is in the best interest of the minor is obvious, and where an emancipated minor is involved.⁴⁹⁵

Finally one must consider the situation in the Civil or Common Law with respect to resolution of conflicts between a parent and child, which is usually when the parent consents to therapy and the child does not. Implied in discussion of the opposite situation, that is where the child consents and not the parent, a principle may be deduced that it is necessary to recognize the child's wishes and to justify overriding them, especially as the minor approaches maturity.⁴⁹⁶ This reflects a more recent approach of the law which has been to realize that attaining maturity is not an overnight event but a process, and should be recognized as such: further, there may be increasing recognition that perhaps a child has a right of veto which arises before he has capacity to consent and which one must justify contravening.⁴⁹⁷ Pilpel⁴⁹⁸ describes this evolution as a change from seeing children as the property of parents, to recognizing them as persons with rights and, with this, a change from their not being able to consent, to being able to do so by common law (or "droit commun") exception, or pursuant to statutory provision and, as a corollary, with at least some right to refuse treatment.⁴⁹⁹

2. Consent to non-therapeutic research

One now moves to the much more difficult area of consent to non-therapeutic medical research on children. The point just discussed is important here, in that it leads to the conclusion that if the child objects to participating in such research, one is not justified in overriding his wishes.⁵⁰⁰ Thus with the mature minor the capacity to consent to beneficial treatment must carry with it an ability to refuse non-beneficial intervention, but whether it also carries the capacity to consent to the latter is a further question.⁵⁰¹ When therapeutic treatment of an immature minor is involved, I have suggested that the parents must be justified in overriding his wishes, but such justification would never be present in the non-therapeutic situation.

In relation to non-therapeutic interventions on minors one is therefore left to deal with the situations of the non-discerning, non-objecting minor and the discerning, consenting minor. The question is whether the parents' "consent" is sufficient and necessary in each case.⁵⁰²

There are many lines of philosophical, ethical and legal discussion⁵⁰³ which can be only briefly outlined here, but all of them have influenced and are influencing the evolving consensus on the

subject. The most interesting and most publicized philosophical argument has been engaged in between Ramsey⁵⁰⁴ and McCormick.⁵⁰⁵ The former is of the view that children incapable of consent may never be used in non-therapeutic research, whereas the latter believes that this is justified where children "ought", as members of the human race, to accept this obligation. Such an obligation would exist when risk, discomfort and pain are minimal and the research is very likely to be useful. In such cases, McCormick argues, parents may give "proxy" consent. There are inherent problems in each view: Ramsey's approach is probably not feasible, accepting the current state of research carried out on children;⁵⁰⁶ McCormick's view probably has a generally unacceptable logical extension. If one can use children as subjects in situations where they "ought" to consent, why apply this rule discriminatorily, that is why not apply it equally to adults who could then be conscripted as experimental subjects within the terms of the "ought", in much the same way as is done for military service? It is in avoiding this difficulty that Toulmin's⁵⁰⁷ modification of McCormick's formula is useful. He says the stress should be on that to which the child (or other incompetent) could not reasonably object. In practical terms the results are the same, but this avoids imputing an obligation to the child and not to others.

The legal development in this area is best traced in the context of live organ donation by children, which is, of course, non-therapeutic for the donor.

In France, such donations, by any person, child or adult, were, like non-therapeutic medical experimentation, initially considered illegal. However, this was modified by the development of a legal doctrine of a "state of necessity", functioning as a justification for the wrong of operating on the donor, when the purpose was to avoid a greater evil, namely the death of the recipient.⁵⁰⁸ This doctrine is applicable to minors capable of discernment in exceptional cases,⁵⁰⁹ but it is not clear whose consent is necessary and sufficient, the minor's alone, the parents' alone, or both.⁵¹⁰

In Quebec the situation is governed by legislation. Article 19 of the *Civil Code of the Province of Quebec* enacts a general rule of inviolability, requiring consent for its valid waiver. Article 20, *inter alia*, enables a minor capable of discernment to consent to *inter vivos* organ donation, or to experimentation, one of the conditions being that no serious risk to the minor's health results from this. The Article's original version also called for the consent of both the

person having paternal authority and a judge of the Superior Court. Quite apart from the problem of determining what amounts to a "serious risk" there was another difficulty in interpreting this provision—it was not clear where effective consent arose, either with the minor, or with the parent or judge or all three. This Article has now been amended⁵¹¹ to provide for the consents of the minor and of the person with parental authority as well as an *authorization* by a judge.

In regard to the effects of the minors and parent's consents under this new provision, in my view the better interpretation is that the minor's consent is constitutive, with the consent of the parents being regarded as enabling or declarative. This view may be supported either on the basis that under the "droit commun" a minor capable of discernment has capacity to consent to a medical intervention,⁵¹² and that Article 20 extends this capacity to non-therapeutic interventions, or that Article 20 grants this capacity *de novo*, provided in either case that its terms and conditions are complied with. Any other interpretation of Article 20 leads to the result that one is taking an organ from, or experimenting on, a minor for another's benefit, without his consent being recognized as the primary although insufficient justification of the intervention. With respect to adults such interventions are not permitted except on the primary basis of the adult's consent and they should not be permitted *on the basis of* a third party's consent with respect to minors. Thus Article 20 legislates "le droit de sacrifier pour autrui"⁵¹³ and extends this to discerning minors in certain circumstances. Whether one is justified in contravening the inviolability of a minor on the basis of some justification other than personal consent is a further question and discussed later.⁵¹⁴

In Common Law jurisdictions the regulation of organ donations by living persons is also instructive regarding consent to non-therapeutic medical interventions on minors. Among the Common Law Provinces of Canada, Ontario,⁵¹⁵ British Columbia,⁵¹⁶ Nova Scotia⁵¹⁷ and Newfoundland⁵¹⁸ have prohibited tissue donation⁵¹⁹ by minors and in doing so, have followed the uniform legislation⁵²⁰ recommended for adoption in all Common Law provinces of this country.

In England there is no legislation governing donation of organs by living persons, whether child or adult, and the rights of parents to consent to medical interventions on their children, although not questioned in the therapy situation, have only been clearly recog-

nized by the courts in reported decisions in recent years.⁵²¹ Some of these cases involved paternity disputes in which blood tests were required and where, consequently, there was an element of non-therapeutic, rather than therapeutic, benefit involved. However in these cases there was no question of the intervention being without benefit to, or contrary to the best interests of the child.⁵²² There is dicta in these cases that has subsequently been used⁵²³ to ground an argument that a parent may consent in the "best interests" of the child, which does not necessarily mean for the child's therapeutic benefit, the latter being the traditional requirement for any consent validating a medical intervention.⁵²⁴ In my view this is an unfortunate extension⁵²⁵ in relation to children incapable of discernment, an extension demonstrated in the American courts' reasoning in the minor, or mentally incompetent, organ donor cases.

In *Bonner v. Moran*⁵²⁶ the court held that a fifteen year old boy could not alone consent to be a donor of skin, but by implication indicated that his parents could have consented.⁵²⁷ In conformity with a view that parents can consent to non-therapeutic interventions on their children, a Connecticut court, in *Hart v. Brown*,⁵²⁸ authorized the parents of seven-year-old twins to consent to the donation of a kidney by one to the other. Similarly in *Nathan v. Farinelli*⁵²⁹ the court characterized its duty not as one of deciding whether or not to allow the operation to take place, but of reviewing the parents' decision. The Court both relied on *Bonner v. Moran* and expressly rejected the psychological benefit test, thus interpreting this case as authority supporting the parents' right to consent in a non-therapeutic situation. In contrast to instances in which immature minors were involved in non-therapeutic procedures, in *Rappeport v. Stott*⁵³⁰ a Massachusetts court held that a seventeen-year-old girl was intellectually, and therefore legally, capable of consenting to a bone marrow donation. This is an application of the "mature minor rule", that is that the consent of such a minor is sufficient.

If one accepts that parents may consent to some non-therapeutic interventions on non-discerning children one must examine the conditions under which the courts have allowed such consent. In this respect a comparison of two cases involving mental incompetents, who are in a directly analogous situation to non-discerning minors as far as capacity to consent is concerned, is instructive. In *Strunk v. Strunk*⁵³¹ the court authorized⁵³² an operation to remove the mentally incompetent donor's kidney for transplantation into his brother. This was done on the basis of the parent's petition and after finding, on very slim grounds, that there would be psychological harm to the

incompetent donor if his brother died, as he would be "saddened". The avoidance of this sadness was equated to psychological benefit. In *Re Richardson*⁵³³ on the other hand, the court held that the parents could not consent, nor could the court authorize the organ donation operation on the incompetent, certainly not in this case since they had found no benefit to the donor; and possibly not in any case.

The development of the test of psychological benefit used in these incompetent transplant donor cases, evolved from the courts' difficulty in finding that the requirement of therapeutic benefit to the person on whom a surgical operation was carried out was fulfilled. This requirement was necessary for the legality of an operation at Common Law.⁵³⁴ This was dealt with by changing the content of the requirement of therapeutic benefit to include not only the traditional element of possibility of physical benefit to the patient, but also psychological benefit, or merely benefit, in the sense that the intervention was in the "best interests" of the donor.⁵³⁵ Thus in instances of non-therapeutic interventions for "inter-vivos" organ donation the presence of psychological benefit, or any benefit, to the prospective factually or legally incompetent donor, seemed to be regarded by the courts as a sufficient condition precedent to an incompetent's or minor's consent, where such consent was possible, or to the guardian's or parents' consent, or to the court's authorization.

This modification of "therapeutic benefit" to psychological benefit was first developed in three Massachusetts cases, each involving kidney donations between twins,⁵³⁶ in which psychiatric evidence was given that there would be "grave emotional impact" on the donor if not allowed to donate. Avoidance of this trauma was characterized as benefit. However, in all these cases the minors concerned could have been regarded as "mature", as two sets of twins were aged fourteen and the other nineteen years. However, it is not clear whether the "mature minor rule" applied, assuming that this connotes equivalence to the competent adult situation with respect to consent and does not have special rules of its own. This doubt is caused because with competent adult donors "informed" consent has come to be regarded as an alternative to, or substitute for, therapeutic benefit; and yet the courts in the cases under discussion, went out of their way to find psychological benefit to these mature minors. Further, these cases do not answer the question of whether the parents' consent alone is sufficient, either with or without psychological benefit, when a non-discerning minor is involved.⁵³⁷

Two cases already mentioned, in which the donor children were seven and six years of age respectively, are of interest in this latter respect. In *Hart v. Brown*⁵³⁸ there seems to have been an easing of the psychological benefit test, to one of lack of “substantial harm” to the donor and substantial benefit to the recipient, as justification for the non-therapeutic intervention.⁵³⁹ In *Nathan v. Farinelli*⁵⁴⁰ there was an overt weighing of costs and benefits to both children on the basis of what was “fair and reasonable”, and the court expressly rejected the psychological benefit test as highly speculative.

These cases and the change in the requirement of therapeutic benefit that they show, are significant when one considers whether parents may consent to non-therapeutic medical interventions on their children. They constitute at least some precedent for saying that parents may consent when the minor is not capable of discernment, when the procedure is not therapeutically beneficial to him, and when, perhaps, it is not even in his best interests. The harm does not outweigh the benefit to the minor in the latter case but rather the justification advanced is that the harm to him is outweighed by the benefit to someone else. In my view this proposition is unacceptable as a general policy, and perhaps even as a particular one. Such precedents must be contained within the strict limits of their facts, that is where a close, identifiable relative is being benefited by the non-therapeutic intervention. This limitation may be achieved by arguing that, at their widest, doctrines of “proxy consent” or “substituted judgment”, historically and in these cases as well, have only been applied to assist close relatives in need.⁵⁴¹ However it is disturbing to realize that a strong argument can also be made for expanding the application of the precedent set by these cases only on the basis of this same fact, that they involved close relatives, usually brothers and sisters. This occurs because it can be suggested that if the court allowed parents to consent to a non-therapeutic intervention when they were faced with such a terrible conflict of interest, between choosing the death of one child and maiming another, they would more readily permit this in the non-therapeutic research situation, when such a conflict is not present.⁵⁴²

In summary I submit that non-therapeutic medical research involving risk, may not be carried out on minors who have not personally given “informed” consent and, in particular, may not be justified on the basis of “proxy” consent. This position is not the same as saying that any such research is never justified. Such a position should also be generalized I suggest to cover other non-therapeutic or doubtfully therapeutic interventions, such as the

sterilization of mental incompetents, or to controversial techniques such as psychosurgery. Similarly the following discussion of the medical research situation, dealing as it does with many of the issues raised by "proxy" consent in relation to such interventions, may also be generalized to those other non-therapeutic or doubtfully therapeutic interventions.

The question then is; short of banning all non-therapeutic medical interventions on children personally incapable of giving "informed" consent, when should they be allowed and how should they be regulated? Firstly, to ensure that the consent of parents is not seen to be a justification, in the area normally referred to as "proxy" consent, one should end the "charade of consent".⁵⁴³ That is the reality of what is taking place must be stated bluntly so that "proxy" consent is not seen as consenting on the child-subject's behalf, but rather as consenting directly to the intervention on the subject. This means dropping the use of the word consent and rather speaking of selection of child-subjects, the child's assent, and the permission of parents.⁵⁴⁴ Although such a change may only be in nomenclature and not reflect any difference in reality, it is, I submit, important for the purpose of developing attitudes and sensitivity to the issues involved. The aim is to distinguish "what a person may do for oneself, [sic] consent, from what one may do on behalf of another, grant permission".⁵⁴⁵

Then, arguably, "no risk" or "minimal risk" non-therapeutic interventions,⁵⁴⁶ may be allowed with the assent of the child where the child is capable of such assent, and with the permission of the parent. In this case one is not contravening the general rule that parents have no authority in non-therapeutic circumstances and may not purport to consent to infliction of harm on their children.⁵⁴⁷ Rather, arguably^{547a} their consent is not needed because of the lack, or insignificance, of any harm or risk of harm.⁵⁴⁸

With respect to more than minimal risk, non-therapeutic interventions, the "mature" minor, subject to proper safeguards of ethical review by a committee and possibly parental permission in some circumstances, ought to be allowed to give "informed" consent. There would also be other conditions precedent to carrying out such interventions, in addition to those normally required. For instance, in relation to medical research, one condition is it must be impossible to carry this out, or conduct it further, on adults. Another is that the studies must be initiated on older children, if this is valid for research purposes, prior to including younger children, even

though the latter are capable of discernment.⁵⁴⁹ Or, with regard to other procedures, for example sterilization, this must at least be the least restrictive and least harmful alternative available.

There is, however, a fundamental problem in allowing more than minimal risk, non-therapeutic medical interventions on minors capable of discernment, and this is the problem of identifying when a sufficient level of discernment is present. A child may be considered legally capable of discernment as young as seven years of age, but this may not indicate he has the necessary discernment to consent to medical research, as has been empirically demonstrated by Schwartz.⁵⁵⁰ This researcher found, that despite careful and detailed effort, children under eleven years of age were unable to be made aware that they were participating as research subjects. Six of nineteen minors aged eleven to seventeen years had some awareness of the research element involved, and of these six, five suffered acute anxiety. If the results of this study are generally applicable it throws doubt on whether one can, or should, use even "discerning" minors as medical research subjects.⁵⁵¹

Thus it is strongly arguable that parents cannot consent to any non-therapeutic medical intervention involving risk, or more than minimal risk, and that such interventions should never be allowed on minors incapable of giving fully "informed" consent at a subjective level.⁵⁵² And yet there may be exceptional circumstances where this is justified, for example where all children are threatened by a serious disease and no other type of medical research except that on children offers any prospect for discovering a cure, or where children are afflicted with a fatal disease and while research on the disease does not offer them any potential benefit, it may nevertheless benefit others with the disease in the future. In such cases the emphasis must be on two matters: the truly exceptional nature of allowing the research intervention^{552a} and further, that although permission or consent of the parents may be a necessary condition precedent, it does not have the effect, in itself, of making the intervention legally valid.⁵⁵³

Rather a system of elaborate safeguards, which include the parents' permission and the child's assent to the extent that he is capable of giving it, must be set up⁵⁵⁴ and a further and adequate justification for conducting the research must be found. In the latter example cited above, of non-therapeutic research on a fatal disease from which a child is suffering, it may be that the patient's "identification",⁵⁵⁵ with future sufferers of the same disease, goes

some way towards this. However a justification such as this must be used with extreme caution and reluctance, or it will open the way to using non-consenting patients incapable of discernment, simply on the basis that there is some connection between a disease from which they suffer and the research. It is only within such a framework of safeguards that one may honour the rule that parents may not consent to any risk of harm or more than a minimal risk of harm being inflicted on their children, while still recognizing that some truly rare situations do exist, where the ethics may mandate the medical intervention being conducted.

3. Institutionalized children

These children deserve special mention and special protection, which means they should never be subjected to non-therapeutic medical interventions or used in non-therapeutic medical research, and exceptional care must be taken in accepting third party permission to any intervention with their physical or mental integrity. In a sense they have a double "disability", that of being children and of being institutionalized and, in the latter respect, are comparable to prisoners.⁵⁵⁶ They are too available, too easily coerced, too little protected by someone with the necessary bond of affection and personal commitment. This bond is necessary for even "proxy" consent to serve its proper function, assuming for the moment this is legally adequate and should be treated as effective. This has been legislatively recognized with regard to medical experimentation in Pennsylvania,⁵⁵⁷ where non-therapeutic research on juvenile inmates of state and county correctional institutions is banned.

The matter is more difficult with respect to therapeutic medical research or to doubtfully therapeutic interventions. However, here there must be a heavy onus on the physician to show that the intervention is carried out with a genuine therapeutic aim for *that* child, that there have not been coercions applied to either the child or parent,⁵⁵⁸ and that there is adequate independent scientific and ethical review of the proposed intervention or research protocol. This includes determining that the procedure is within the definition of therapy.

It is worth noting that in the United States, the National Commission in its draft paper on "Research Involving Children"⁵⁵⁹ and in its subsequent "Report and Recommendations"⁵⁶⁰ on this topic, does not distinguish between therapeutic and non-therapeutic

medical research for the purpose of deciding what safeguards should apply in a particular research situation. Rather, benefit to the child-subject is one factor taken into account in deciding whether to approve the particular research. Within this wider context special provision is made for children who are wards of the state or institutionalized, in that with some narrow exceptions there is a general prohibition on including them in medical research.⁵⁶¹

4. “Consent” by the state and its refusal to recognize consent with respect to medical interventions on children

Just as the state can authorize treatment of children against the wishes of the parents, under its *parens patriae* power or specific statutes it can intervene for similar reasons to prevent unjustified treatment to which the parents have consented. It is interesting here to consider whether parents’ power over their children as well as the power of the state to intervene, is original or derivative. The more acceptable view is probably that the parents’ power is original, but limited by the rights of the child, and that the state’s power is derivative, both from the parents’ power and the child’s rights, either of which it can enforce for proper ends. In the process of maturation, one can then argue there is a progressive handing over of power from parent to child, so that one finally has a competent adult with individual, original rights, which are limited only to the extent specified by law.

The bases on which the state may intervene to authorize or prohibit medical treatment or research may be simply under its general protective power over minors or those unable to protect themselves. Or it could be pursuant to child abuse legislation⁵⁶² such as that in California, where it is a misdemeanor to endanger the health of a minor or to subject him to *unjustifiable* mental or physical suffering.⁵⁶³ Levine⁵⁶⁴ suggests that a parent who consents to a child participating in non-therapeutic experimentation may be liable, with the physician, for conspiracy to commit child battery. Hershey and Miller,⁵⁶⁵ in a list of possible actions arising from the same circumstances, include first, court determinations that the child is “dependent and neglected”, with the possible consequences of parental loss of custody and the child being made a ward of the state. Secondly, they list criminal liability of both the parent and researcher where harm is actually inflicted on the child as part of the study. If

such a situation amounts to child abuse then there may be further liability, since failing to report an incident of child abuse about which one has knowledge, may in itself be an offence, as it is for example in Quebec.⁵⁶⁶

C. CONSENT AND FOETUSES AS PATIENTS OR SUBJECTS OF MEDICAL RESEARCH

The most difficult problem here is consent as it relates to medical research on foetuses. This is not only a controversial topic in itself, but it often involves another ethically polarized area, that of induced abortion.^{566a} Therefore some reference to the arguments put forward regarding this practice are necessary to an analysis of consent in relation to medical interventions on foetuses. If one believes abortion to be morally unacceptable, then it is difficult to accept arguments justifying research on aborted foetuses as their availability depends on a moral wrong. It is argued against this that the ethics of abortion are irrelevant, as a utilitarian justification applies, and that as the foetuses have been aborted it is simply wasteful not to use them for research. The problem with this rebuttal is that the act making the foetuses available is a deliberate human intervention, and in my view it is not clear that one can morally apply utilitarian arguments of waste as justification in such a situation. The same type of arguments could be applied to prisoners, and yet we take a different approach, probably because society is seen as having acted to place them in a situation of availability where they may be coerced. Thus we make a distinction between this "artificially created" type of availability or coercion and that arising in the "ordinary course of events", for example pressure from one's family group. As a result we see persons affected by the former as needing more, rather than less, protection.

Depending on the proposed future of the foetus, it may be included within one or more of the categories of patient or research subject already discussed. Whether it should be governed by the rules suggested for consent to treatment and research on children while still *in utero*, is a matter of debate, and to some extent, relates to one's views on the acceptability of abortion and the basis upon which one justifies and performs it. If one regards the foetus as a person, in fact or law, from conception, or from implantation, or from viability, or from some other arbitrarily determined time, then at that point in time abortion, for many people, becomes unacceptable. But whether or not abortion is acceptable past this point in time, the logical corollary

of recognizing the personhood of the foetus is that from that time, the foetus *in utero* must be treated with respect to consent to medical interventions on it, according to the same rules as an infant child.

With respect to medical research on the foetus *in utero* prior to its personhood being recognized, it is very much a moral value judgment as to what experimentation may be consented to on its behalf. I suggest that for reasons of distributive justice one is not entitled to discriminate between foetuses going to term and those to be aborted. The rule must be that only interventions which would be allowed on a foetus going to term, which interventions are governed by the criteria applicable to treatment or research on non-discerning children, are allowable. There is, however, one modification which must be made because of the physiological unity of the mother and foetus. This is that the mother may consent to therapy for herself, and even to non-therapeutic research directed towards her when the latter involves at most minimal risk for the foetus, and even if it carries more than such risk if it is necessary therapeutic experimentation for the mother.

It is sometimes argued that if one can intervene to kill the foetus by abortion, why not do so in a more socially useful way, by experimentation?⁵⁶⁷ One of the answers to this question is that even though the woman may have a right to an abortion, this does not necessarily mean she, or anyone else, has the right to consent to experimentation on the foetus. In other words if one recognizes a right to have an abortion this must be premised on a woman's right which in the circumstances overrides rights of the foetus; when there is no right of the woman being upheld, as in experimenting on the foetus, its rights may not be ignored or waived by consent.

There is also a danger in allowing consent to minimal risk research on foetuses. Although this does not seem very different from the situation with regard to non-discerning children, where it has been suggested that such research may be acceptable, a subtle distinction has been and may be made. This is that the assessment of risk is subjective and with a foetus intended for death by abortion, in comparison, almost any procedure can be considered minimal risk. That is "risks to the foetus-to-be-aborted may be considered minimal in research which would entail more than minimal risk for a foetus-going-to-term".⁵⁶⁸

Assuming that one finds it ethically acceptable to conduct some or all forms of medical research on one or more "categories" of

foetus, that is “to-be-aborted”, aborted, non-aborted, viable, pre-viable, living or dead, there are still problems of “informed” consent. If the foetus is not to be aborted the situation is directly analogous to that governing children incapable of discernment, and the parents may “consent” or give permission for treatment or research on the same conditions and in similar circumstances. When abortion is involved the matter is more complicated as there is an objective conflict of interest, and probably not sufficient mutuality of interest, at least between the mother and the child, to allow the consent of the mother on its behalf to be recognized as legally valid. However, in the United States the National Commission and the D.H.E.W. agreed to the contrary. “that a pregnant woman need not be presumed to lack interest in her fetus even when she has decided to terminate her pregnancy; thus she may validly be asked for consent for research involving the fetus”.⁵⁶⁹

The Peel Report⁵⁷⁰ is consistently vague with respect to the consent required for research on the foetus. It speaks of research, presumably therapeutic, on a viable foetus to which “the parent’s consent can normally be inferred”, (*quaere*) and then of “areas of research which whilst not jeopardizing the health and welfare of the foetus are not of direct benefit to that particular foetus. In such cases [the members of the Advisory Group] consider that express consent should be obtained from the parent”.⁵⁷¹ The Report then deals with the dead foetus, where if the United Kingdom *Human Tissue Act*⁵⁷² applies, the consents required under this must be obtained and if not, there must be “no known objection on the part of the parent who has had an opportunity to declare any wishes about the disposal of the foetus”.⁵⁷³ The latter alternative given here, apparently implements the opinion that “[w]here the separation of the foetus from the mother leads to the termination of its life there is no statutory requirement to obtain the parent’s consent for research, but equally there is no statutory power to ignore the parent’s wishes”.⁵⁷⁴ The provisions regulating consent to research on the pre-viable foetus while still alive, are the same as for the dead foetus.⁵⁷⁵ This probably explains the complexity of the terminology used in the passage last cited above, as the words “dead foetus” could just as easily have been used if this was all that was intended to be covered within these terms, in comparison to the terminology needed if the provision is meant to extend to the living pre-viable foetus, as this provision, in all likelihood, does. It is also possible that the Advisory Group considered such a pre-viable foetus to be already dead,⁵⁷⁶ which raises the difficult but essential distinction between the process of

dying considered medically, and the event of death considered ethically and legally.

Some commentators believe that, as a matter of law, consent to experimentation on the foetus may not be required at all, "because there is no interest in young foetuses that needs to be protected by the use of consent",⁵⁷⁷ or because the foetus is a tissue specimen removed from the mother and the mother's consent to the abortion surgery covers any dealing with such specimens that the hospital's pathology laboratory deems to be fit and proper.⁵⁷⁸ It has also been argued that one does not need the consent of the foetus, and therefore, nor the "proxy" consent of the parent, to foetal research, because if this were the case one would also require "proxy" consent to abortion on behalf of the foetus.⁵⁷⁹ In fact this latter argument shows why "proxy" consent to foetal experimentation involving abortion should not be regarded as valid, as it is a protective device for those "unable to speak for themselves" and one can never justify using it to achieve the very opposite of its intent".⁵⁸⁰ The conclusion then should not necessarily be that because "proxy" consent is not needed to abortion it is therefore not needed to research on the foetus, but perhaps that the research requiring such consent may not be carried out.

In relation to defects of consent with respect to consent to foetal experimentation, coercion in the form of payment can present one of the major problems. The D.H.E.W. Regulations provide that "no inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of" research⁵⁸¹, and the Peel Report's "Recommended Code of Practice" states there must be "no monetary exchange for foetuses or foetal material".⁵⁸² This approach, I submit, is an essential safeguard, not only of the foetus, but also of the mother, in order to ensure she is not coerced into decisions she may later regret.

There is one final question to be raised in relation to consent to medical interventions on the foetus, and this is how does consent to such interventions affect the foetus's right to sue if, and when, it becomes legally recognized as a person? Once the foetus is born, and certainly if it is viable, there is now no doubt that in all relevant jurisdictions it has the protection of law and remedies for pre-birth injury available to it.⁵⁸³ In Civil Law jurisdictions the "nasciturus rule" seems to apply, which means that any right of the child to sue for damages for personal injury only accrues on viable birth. It is not as clear that this is the case in Common Law. The situation between

various states of the United States of America, differs in that there are some precedents which require the injury to have occurred after viability for recovery of damages, which recovery does not, however, depend on live birth, and other precedents which hold that it does not matter when the injury occurs, but the cause of action only accrues on live birth. The latter is the approach taken in England, Common Law Canada and Australia.⁵⁸⁴ Such remedies, provided their necessary conditions precedent were fulfilled, would be applicable in the case of a foetus suffering harm from *in utero* medical interventions, whether later aborted or not, depending on the effect that the consent of the parents has on the child's right to sue. In my view this effect would vary, according to whether the treatment of research was therapeutic or non-therapeutic, and whether the foetus was born as a result of induced abortion or not. In the case of therapy or therapeutic experimentation where abortion was either not involved at all, or was medically indicated as "pure" therapy for the mother, the parents' consent would probably bind the child, who should be taken to have had his right to sue waived on his behalf. As one moves along the continuum to clearly non-therapeutic research on the foetus and "abortion on demand" the parents' consent becomes legally less effective in binding the child, until it is of no effect at all.

D. CONSENT AND MENTAL INCOMPETENTS AS PATIENTS OR SUBJECTS OF MEDICAL RESEARCH

There are two disabilities covered by the term mental incompetency—legal and factual incapacity, either of which may be temporary or permanent.⁵⁸⁵ When the latter incapacity is present, the situation is analogous to medical interventions on non-discerning children, with the same "caveat" present about involvement of institutionalized persons in medical research.⁵⁸⁶ Neville⁵⁸⁷ analyzes the reasons why institutionalization should be a bar to using such persons as research subjects, which really amounts to a delineation of coercive factors which may affect the validity of consent. He says that civilized protections, to ensure that one person does not have undue and inappropriate power over another, are not effective in this situation. He maintains this is so because such protections require a right to dissolve personal relationships and to belong to contrasting groups for support; and they suppose a practiced development of

private judgment and an environment that “does not conspire to subject the individual to the interests of the environment itself”.⁵⁸⁸

When mental incompetents are involved in medical interventions, special care is needed in assuming or accepting the concordance of interest of the parent or guardian and the incompetent for the purposes of “proxy” consent, or any granting of permission. With a child one has the promise of life in the future as a fully legally capable person. The lack of this feature with respect to some mental incompetents, may alter judgments made by others concerning them, to the effect that their interests are more likely to be sacrificed. As with children, account must also be taken of the degree of the factual incapacity and assent of the patient sought to the extent that this is possible. This is so even when the intervention is independently justifiable because, for instance, it is therapeutic. Likewise, more weight should be given ethically and legally to such a person’s objection to participation than would be to his consent, so that his power of veto is stronger than his ability to consent.⁵⁸⁹

This shows that in determining what is an ethically and legally adequate consent to a medical intervention on a mentally incompetent person, it is necessary to examine both legal and factual incapacity, the former of which may or may not coincide with the latter, and further to recognize that institutionalization is not *necessarily* conclusive of either.⁵⁹⁰ Where a person is factually incompetent he is also legally incompetent, but he may have been declared legally incompetent, by a process of law such as commitment or interdiction, and at some later time be factually competent.⁵⁹¹ Traditionally a functional test of competency in relation to managing one’s estate was used as the basis for a declaration of legal incompetency, which, as a corollary, was often aimed at protecting the incompetent’s property and not his person. Such a declaration, however, was generally regarded as rendering the person subject to it incompetent in all respects. This global effect should be re-examined and a person who is factually competent in regard to medical decision-making should not be deprived of this right. Rather, a person should only be declared to be totally legally incompetent where this is necessary to protect both his person and his property.

Legal processes of commitment or interdiction have the effect of vesting the power to exercise some, or all, of the incompetent’s rights in a guardian, tutor, or curator. It follows from the fact that the aim of this process is protection of the incapable person, that if the protector has the right to consent to violation of his ward’s bodily integrity, he

can only do so for the benefit of the person under his care.⁵⁹² This, I submit, is an even clearer case than when the same arguments are applied to “proxy” consent involving children, because there is absolutely no question of custody coming into play, that is custody in its ancient sense of ownership rather than care. Thus, I propose, a guardian or tutor of a mental incompetent may only consent to therapy or therapeutic research undertaken for the benefit of the incompetent. Apart from lacking legal ability to consent on any other bases, there is a strong policy reason to limit the “proxy” consent to this extent, and that is the otherwise present danger of taking account of social worth in the selection of subjects for risky medical research.⁵⁹³

When one examines legal doctrine, it is the unanimous view of Civil Law writers that a tutor or curator of a legally incompetent person may not consent to non-beneficial medical interventions being undertaken on the latter.⁵⁹⁴ Kornprobst⁵⁹⁵ looks at the various categories of legal incompetents under French law, and says that “petits mentaux” must consent for themselves, whereas for “internés” a relative may do so, while for “interdits” a tutor may consent, and with “prodigues”, as the tutor is only appointed to their goods, they retain the right to give personal consent. Thus those who are legally not permitted to consent for themselves are excluded from participating in non-therapeutic medical interventions, as another may not consent to a procedure not for their benefit. With those able to consent for themselves, assuming the proposed non-therapeutic medical intervention is otherwise permissible, it is a question of fact as to whether they have given the necessary “consentement libre et éclairé”.

The general regime for mental incompetents is essentially the same in Quebec⁵⁹⁶ as that just outlined, but one must take account of the effect of Article 20 of the *Civil Code of the Province of Quebec*. I suggest that in conformity with the general principles of the Civil Law, the desirable interpretation of this Article is that it does not extend to allowing “proxy” consent of the legal representative to non-therapeutic experimentation on, or organ donation by, a factually or legally incompetent person.⁵⁹⁷ Further, I submit, the person himself, while subject to a decree of legal incompetency taking away his power to consent to medical interventions, may not consent within Article 20, even though at the time he is factually competent.⁵⁹⁸ This, in reality, is to interpret the word “consent” in Article 20, as meaning and requiring for fulfillment, personal consent

given by a person with full legal and factual capacity, except if such person falls within the express provisions covering minors.

In Common Law the matter is not clearly settled as to the extent to which a legal guardian may consent for an incompetent,⁵⁹⁹ although one may draw an implication relevant here from the fact that the Common Law Provinces of Canada have prohibited the mentally incompetent as *inter vivos* organ donors,⁶⁰⁰ and the Australian Law Reform Commission proposes the same rule.⁶⁰¹ There is again no doubt that the guardian can and must act for the benefit of the incompetent and the problem therefore arises in relation to consent to non-therapeutic medical interventions. The live organ donor transplant cases in the United States of America which involved mentally incompetent donors, and which have already been discussed,⁶⁰² are instructive in this regard. They show that a court may or may not feel itself free to authorize, or to validate "proxy" consent to such a non-therapeutic intervention on the incompetent.

Also with respect to use of the doctrine of substituted judgment⁶⁰³ in relation to such interventions, a further comment should be made here, as this doctrine traditionally has closer legal links with mental incompetency in its strict sense, than with decisions involving non-discerning children and hence may be more readily applied in the former area. This doctrine has been used for one hundred and fifty years to provide for needy dependents from incompetents' estates, but it is another matter to use it as a justification to invade another's bodily integrity, especially when it is much easier to be altruistic on behalf of that other rather than oneself. The *Kaimowitz Case*⁶⁰⁴ is a strong precedent that the Court will not recognize "proxy" consent to experimental treatment of doubtful therapeutic value, to say nothing of non-therapeutic interventions on a mental incompetent.

It is necessary now to mention the problem of the sterilization of mentally incompetent persons,⁶⁰⁵ which is a non-therapeutic, non-experimental intervention, but which in some circumstances, is arguably in the "best interests" of the person subjected to this procedure. Great care is needed to ensure that the real, but latent, "best interests" taken into account are not in fact those of the community rather than of the mental incompetent. If the former were the case, which should never be, the situation would much more closely resemble that of non-therapeutic medical research. But where such decisions are based solely on the best interests of the mental incompetent, cases⁶⁰⁶ determining whether "proxy" consent

to the sterilization procedure is valid may be regarded as special examples of courts' reactions to a unique problem, with no direct application outside the realm of sterilization to other non-therapeutic situations especially as far as doctrines of "proxy" consent are concerned.

Another factor which must be taken into account in Common Law jurisdictions is the potential law-making effect of recognized current professional practice. For instance the proposed D.H.E.W. Regulations in the United States of America, limit medical research on institutionalized mentally disabled individuals to that "related to the etiology, pathogenesis, prevention, diagnosis or treatment of mental disability or the management, training or rehabilitation of the mentally disabled and [which] seeks information which cannot be obtained from subjects who are not institutionalized mentally disabled".⁶⁰⁷ It could be that these Regulations will have a general limiting effect on what is legally acceptable medical research on such persons. This would occur if such Regulations defined the scope of what a guardian may consent to on behalf of a mental incompetent, assuming this may extend somewhere beyond direct therapeutic benefit, or if they outlined the extent and content of acceptable medical practice with respect to such a person.

Some Codes relevant to human experimentation are informative with regard to consent to medical interventions on mentally incompetent persons. The Nuremberg Code⁶⁰⁸ does not provide for consent by the legal guardian of an incompetent, although Mishkin⁶⁰⁹ reports that Ivy who drafted it had included this, but it was omitted from the Court's judgment in which this Code was first handed down probably because it was irrelevant to the case. Under the Declaration of Helsinki, as with children, the legal guardian can consent to research on his mentally incompetent ward.⁶¹⁰ The United Kingdom Royal College of Physicians Committee on Ethics⁶¹¹ would permit negligible risk, non-therapeutic experimentation on mental incompetents with the consent of the guardian, giving, as the justification for this approach, the advancement of medicine. In contrast, English "staff volunteer" research subjects must be of "full age and sound mind".⁶¹² The American Medical Association Guidelines⁶¹³ allow the legal representative to consent to non-therapeutic experimentation on a mental incompetent, but only where "mentally competent adults would not be suitable subjects" and the circumstances are such that "an informed and prudent adult would reasonably be expected to volunteer himself or his child as a subject." There is an important proviso that "[n]o person may be used as a subject against his will".

But notwithstanding this safeguard I query the legitimacy of the previous criteria, as they require that competent adults are not suitable subjects and then that the circumstances are such that they would be expected to volunteer. It is much easier to get someone to agree to participate in unwelcome tasks where this is clearly not possible, than to obtain the same agreement when faced with the reality of participation. Thus, in delimiting the area of acceptable research, mental incompetents may not be protected by this provision to the same extent that "normal" adults would be. This provision in the Guidelines is meant to be an objective test of the acceptability of the "proxy" consent of the guardian. But I suggest that one also should insist upon subjective acceptability, which requires both criteria couched in terms that demand affinity of interest between the guardian and the incompetent, as well as that the research be subjectively beneficial to the person involved.

The point is that all three elements necessary for valid consent, capacity, voluntariness, and information, are suspect with mental patients and, when doubts are present as to all of them, there must be a strong presumption that the personal consent of the person is invalid. Further, there are special problems with protection of privacy in respect to mentally incompetent persons, particularly in psychiatric research, in which the mentally incompetent are probably more likely to be involved than other members of the community.

Such factors indicate that the need for fully informed personal consent is greater and certainly not less, with respect to non-therapeutic medical interventions on mentally incompetent patients, than with "normal" patients. Even looking to the only available alternative, "proxy" consent, in relation to children unable to consent for themselves I have argued⁶¹⁴ that the scope of proxy consent should be strictly limited to therapeutically beneficial interventions or at most to minimal risk ones, and there would be no justifiable or logical reason for having a different rule apply in the case of mental incompetents. As Frenkel⁶¹⁵ says, a guardian who could consent to non-therapeutic experimentation would have a right over the incompetent's body not far from slavery. And perhaps the acceptance of slavery in 1667 explains why, at that time, the use of a mental incompetent as an experimental subject for the transfusion of sheep's blood⁶¹⁶ was apparently acceptable and why it should not be today.

E. CONSENT AND PRISONERS AS PATIENTS OR SUBJECTS OF MEDICAL RESEARCH

In different factual circumstances, and in a different form, medical treatment of prisoners and their involvement as subjects of medical research raises many of the questions already discussed, for instance, the issues related to institutionalization and its effect on voluntariness of consent. Some types of medical procedures which have been looked at in a more general context, may need "special treatment" in relation to prisoners. For example, even if psychosurgery is acceptable therapeutic experimentation on consenting members of the non-institutionalized population, are the dangers of abuse, or the difficulty of obtaining "informed" consent, too great in the prison setting to allow it to be performed on prisoners? Further, even if consent is possible, is it appropriate or acceptable to allow a method which irreversibly "neutraliz[es] the violent prisoner or political dissident"⁶¹⁷, as a means of dealing with the perceived problems such persons pose to society? For the purposes of the present discussion, I will assume that the prisoner has factual, mental capacity and is adult. If this is not the case the prisoner must not only be safeguarded as such, but safeguarded under the protections applicable to any other relevant "special" category, such as mental incompetency or minority.

The most acute problems involving a prisoner's capacity to give "informed" consent arise in the medical research context and it is from this base that the difficulties will be examined. Other situations, including therapy, involve the same considerations with respect to consent, but the rules applicable in the latter may be less stringently applied or a wider range of justifications may be present. However, as with all disadvantaged persons, one should start with the presumption that the strictest and most protective rule applies and any derogation from this must be clearly justified. For this reason an examination of consent in relation to conducting medical research on prisoners is particularly worthwhile.

First a problem arises with respect to legal capacity, as a prisoner was traditionally regarded as losing all his rights with imprisonment.⁶¹⁸ But this has been increasingly modified and one hopes that there will be full acceptance of the idea that a prisoner retains enjoyment of all civil rights. However he may partially or totally lose the right to exercise some of these rights during his imprisonment, either personally only, or also by way of an agent or mandatory.⁶¹⁹ A prisoner should only lose the exercise of those rights

essentially connected with the fact of imprisonment, such as loss of the right to freedom of movement, or loss of those rights affected by the necessity to examine the prisoner for contagious disease. Any *additional interference* with the prisoner's physical or mental integrity must be with his fully "informed" consent. The attitude to be adopted, I suggest, is that as the prisoner's rights as a human person are necessarily curtailed to some extent, he is entitled to more protection. This added protection should not, as it often is, be confused with leniency, "soft-treatment" or pampering of prisoners. Such protection must include, although it should not be limited to, the right of a prisoner to appeal to a court of law to vindicate his right to inviolability.⁶²⁰ However, it seems that courts have been reluctant to interfere in the internal affairs of a prison,⁶²¹ and where this is the case, then a necessary but not sufficient condition precedent to conducting medical research is absent and experimentation on prisoners cannot be justified. How far such a condition should apply in relation to therapy is a more difficult question. It is not relevant when the prisoner gives "informed" consent to such an intervention, but it probably is where he refuses therapy.

As to other necessary conditions precedent to conducting medical research on prisoners, there is at least one commentator who believes that one is never, under any conditions, justified in using these persons as research subjects. Bronstein⁶²² argues that the distinguishing and prohibitive element in the use of prisoners as subjects, is the involvement of the state and the necessary rights it has over the prisoners' bodies simply by virtue of the fact of imprisonment. He makes the thought-provoking statement that "[i]t is not so much the actual, occasional abuse of captive human subjects, but the potential for abuse which concerns [him]".⁶²³ Thus it is not necessary to show abuses to invalidate experimentation in prisons, because the "potential for abuse" is sufficient to do this. It is important to consider these matters because it makes one realize that a discussion of "informed" consent in relation to the use of prisoners as research subjects is not enough, as there may be a duty to not even request the prisoner's consent to participation in the experiment.⁶²⁴ Kilbrandon⁶²⁵ states this in a very effective way when he says that to put a man in prison is to deprive him of a large number of consents, therefore it is distasteful to confer on him a consent which is not for his own benefit.

An argument contrary to the above views advocating prohibition of medical experiments on prisoners, or only allowing it under much more restrictive conditions than apply to the unconfined population,

is that prisoners should not be deprived of any more rights that accrue to other members of society, than absolutely necessary. One such right is that of personal inviolability of both mind and body, any exceptions normally depending on consent. And thus the corollary, the right to consent and the right not to consent. For reasons quite apart from medical experimentation, for instance to give a legal right of action against brutality in prisons it may be important to retain for prisoners these rights to inviolability, and to consent, and not to consent. Therefore, in the context of medical treatment or research, the right to consent should not be abrogated for fear that the rights associated with it, that of inviolability and the right not to consent, will also be affected. Rather its exercise must be safeguarded. This is expressed by Ramsey in the following words: "I am one who happens to believe that prisoners have not been and should not be drummed out of the human race. They ought, therefore, not to be excluded in principle from the community of risk-filled human consent to good purposes, even if the needed practical protections for them are so formidable as to prohibit the general use of prisoners in medical research."⁶²⁶

It may be that if research participation is seen as a privilege, it should not be allowed because distribution of this privilege can become a coercive tool in the hands of wardens and prison authorities, thus affecting the voluntariness of prisoner's consent. This is related to another reason for not allowing research on prisoners. It is that the attitude of prison staff towards prisoners often leaves much to be desired and may amount to coercion to consent, or even ignores, in all but theory, the necessity for free and informed consent. For instance, with respect to prisoner experimentation, a warden at Montana State Prison stated: "we want our prison to be a living laboratory for the people of Montana . . . There should be no conflict in offering *our* physical and human resources [prisoners] to other disciplines . . ."⁶²⁷

Further, some arguments put forward in support of prison experimentation rely on the *control factor* inherent in imprisonment, as an advantage justifying research on prisoners taking place. But these arguments themselves provide further arguments *against* using prisoners, because they raise serious doubts about the validity of the consent given. Examples of such reasoning are that it is beneficial for experimental purposes to be able to totally control the subjects,⁶²⁸ and the experimentation and the rewards it offers may themselves augment the effective power of the prison authorities over prisoners. Newman⁶²⁹ found a reason given to justify the use of prisoner

subjects was the doubtful altruism that wardens, as public officials, were interested in promoting science and, perhaps more realistically if still not acceptable, in promoting a research program which helps the training and education of prisoners. Both these words, training and education, may be used in their genuine sense, but may also be euphemisms for establishing and justifying a more effective system of control of prisoners, without corresponding educative benefit to them. Thus the very advantages of using prisoners—their availability, the convenience they offer as subjects, the ease with which they can be controlled—are precisely the factors throwing doubt on the validity of their consent and weighing against their participation in medical research.

There is a further problem in relation to obtaining "informed" consent from prisoners and this relates to the informing of the doctor by the patient or research subject. It is usually taken for granted that this occurs in "normal" situations, or if not, and the doctor has not been negligent in failing to enquire, the patient or subject runs the risks associated with his non-disclosure. A presumption that a prisoner has disclosed all relevant facts, which disclosure affects the assessment of risk and the information the doctor should give to the patient or subject, may not be justified in the prison setting. From the community's point of view it has been suggested that prisoners should not be used as experimental subjects because they may not be medically normal and that therefore the results of research may be obscured or distorted.⁶³⁰ This distortion may occur as a result of latent disease or deliberate concealment of known conditions. Such concealment is more likely with prisoners than members of the unconfined population because, it is said, prisoners are an anti-social group,⁶³¹ because there are pressures on them to participate as subjects, and because of other collateral reasons. Such a reason would be for instance holding that medical records of prisoners are the property of the state, in which case a prisoner may be fearful of disclosing some medically significant facts.⁶³² One way of verifying results from trials on prisoners would be to use a "free group" control. This may also have ethical and legal advantages in that it would show that the risk level was acceptable to members of the general population, which would be one factor in assessing whether the prisoner's consent may have been coerced, and would represent a move towards more equitable distribution of the burdens of research.

There is one very special class of prisoner and of experimentation which must be mentioned, and this is the prisoner condemned to death. The question is whether the execution should be allowed by

way of experimentation.⁶³³ Some authors⁶³⁴ suggest this is acceptable with full and clear consent,⁶³⁵ others, with whom I agree, reject it.⁶³⁶ This is at least one instance in which consent should be irrelevant with respect to “medical” interventions on prisoners, the intervention in this manner itself being prohibited.

There is another relevant question in relation to obtaining “informed” consent of prisoners and this is to what extent does medical experimentation occur in prisons? If the requirements in relation to “informed” consent to therapeutic or non-therapeutic research are more stringent than with therapy, the identification of research becomes very important. This is a very difficult question to answer for two reasons. First it is possible that some activities which would be classed as experimentation by one researcher may not be by another; and secondly, it is difficult to survey prisons.

The first reason is particularly affected by how one views crime and prisoners in general. For example, Visscher sees behaviour modification experiments on prisoners as “therapy for sick people”.⁶³⁷ Such a classification will profoundly alter the characterization of any activity as either therapy, research, or therapeutic research, which in turn may determine the ethical and legal validity of the procedure, including the consent required.

With regard to the second problem, it is clear that in the United States of America for example there is a great deal of medical experimentation on prisoners, but the real scope of this is unknown.⁶³⁸ In the United States, the National Commission conducted a survey on the extent of research involving prisoners. The report shows in general terms⁶³⁹ that in the majority of states, research on prisoners is allowed and that drug companies are heavily involved. Evidence was given to that National Commission that, “in none of the countries surveyed [which included Canada, France, United Kingdom and Australia] was it found that prisoners are used as volunteer subjects for medical projects, and we know of no countries other than the United States where this is done”.⁶⁴⁰ This is consistent with Dickens’ statement, that the federal and provincial governments of Canada do not approve research on prisoners,⁶⁴¹ and with the British Medical Journal report that it is generally accepted that there should be no research trials carried out on prisoners in the United Kingdom.⁶⁴² However, one would need careful evaluation of the medical and other procedures allowed in prisons to determine that there was no research taking place, even though this may not be as overt as drug trials carried out by pharmaceutical companies.⁶⁴³

It is possible to eliminate the remaining theoretical possibility that medical research is taking place in prisons, and hence the problems of “informed” consent associated with this, by banning such research in prisons. With regard to codes or legislation, I have already noted that the Nuremberg Code and⁶⁴⁴ initially, the Declaration of Helsinki⁶⁴⁵, prohibited research on prisoners, but the latter has now been changed.⁶⁴⁶ Several American States have banned⁶⁴⁷ or regulated⁶⁴⁸ the use of prisoner subjects and, in March 1976, the Director of the United States Federal Bureau of Prisons announced that all biomedical research in federal prisons would be discontinued.⁶⁴⁹ As far as I have been able to ascertain, the only other relevant jurisdiction which has legislation in this field, is France. There the *Code de procédure pénale*, forbids all medical or scientific experiments on prisoners.⁶⁵⁰

Now, assuming that after analysis of all factors, one favours allowing some medical research on prisoners with, among other safeguards, their “informed” consent, what are the problems inherent in this? I have assumed the prisoner has factual and legal capacity, thus difficulties associated with lack of these are eliminated and the problems which must be dealt with are ones relating to informing and consenting.

Leaving aside deliberate deception, which is not normally acceptable with any research subject,⁶⁵¹ informing a prisoner adequately may be a problem even with the best intentions. Ayd⁶⁵² found that prisoners volunteered before an explanation of the research was given, suggesting that their motivation may have been irrational and thus, he suggests, ethically unacceptable. But the same phenomenon has been observed in non-prisoner organ donors,⁶⁵³ and it is therefore debatable whether this factor alone should exclude prisoners. Martin *et al*⁶⁵⁴ investigated the degree to which prison volunteers were informed, and found it was low and no greater than with non-volunteers. They noted further that assessment of risk was not a factor in volunteering. Whether consent should be recognized as legally valid when in a given instance an adequate informing process has taken place, regardless of its real effectiveness in influencing the subject’s decision-making, is a value judgment which depends on many of the same factors involved in deciding whether subjective, as opposed to objective, comprehension of information should be required.⁶⁵⁵

Assuming that one has fulfilled the legal requirements for informing the prisoner, the next step is consenting and the major

problem here is voluntariness or defects of consent: coercion, duress, and undue influence, arising from even the most advantageous circumstances in which a prisoner may find himself. Often, in practice, such defects arise from the fact that incredibly sub-standard living conditions augment this unavoidable element of coercion inherent in imprisonment. The coercive factors which have been identified in prison life are multiple and can be broken down into two major sub-groups: the effects of institutionalization, and those of deprivation. The former sub-group has been mentioned in relation to institutionalized mental incompetents and is a psychological phenomenon that persons may exhibit who have been confined for a period of time. This phenomenon includes an inability to make decisions and a dependency on those in authority.⁶⁵⁶ It would need to be seriously taken into account in assessing the true degree of voluntariness that a decision to be an experimental subject represents, and hence in assessing the legal validity of such consent.

The more extrinsic coercive factor is deprivation, which, apart from the necessary deprivation of liberty, includes: inadequate medical care⁶⁵⁷ and loss of freedom of choice of a physician;⁶⁵⁸ grossly sub-standard living conditions, including the lack of basic articles or amenities for personal hygiene; a lack of money, especially if it is possible to provide better conditions for oneself as a prisoner with this; no, or little, opportunity to fulfill the need to work *per se*, quite apart from monetary reward for work; boredom, so that the experimental situation offers interest, an exciting change, and the transfer to the hospital ward is seen as a vacation; and finally a lack of company of the opposite sex.⁶⁵⁹

Deprivation may also give rise to secondary coercive effects in two ways. First, the ability to volunteer as a subject, and thus avoid some deprivation, may be seen as a privilege in which case it may be used to coerce certain behaviour. Although this does not represent coercion to consent to research, such a factor increases the general coercion present in the prison situation. Secondly, deprivation is linked to coercion directly affecting consent if there is, or a prisoner thinks there is, any possibility of his volunteering to be a subject being taken into account in either a parole or release decision. It is especially important with regard to prisoners to keep in mind their particular deprivations and hence the possible coercive effects of non-monetary forms of payment, from early parole or reduction of sentence which are probably the most coercive, to better or some medical care, and then to minor "luxuries" as rewards, bribery, or pressure, all of which are unacceptable.

This multiple deprivation, which Morris⁶⁶⁰ calls a ‘‘poverty of alternatives’’, probably explains why prisoners and low income groups are more willing to volunteer as medical research subjects⁶⁶¹ and therefore why the validity of their consent should be more suspect. Meyer⁶⁶² demonstrates this dramatically when he shows that prisoners act as subjects for one-tenth the pay of non-prisoners and further that prisoners are twice as willing to participate in any experiment as would be an unconfined person, *even in the absence* of cash payment to the prisoner. This, he says, may be analyzed in terms of opportunity costs. Because the prisoner is so deprived relative to other members of society, he sees himself as having less to lose and more to gain by participation, whereas the same ratio does not apply to a free person.

The reasons given by prisoners for participation in medical experimentation are altruism, money and respect,⁶⁶³ not necessarily in that order. Probably altruism and respect are acceptable coercions, money or other payment may not be. There is a conflict between doing equity and avoiding coercion in paying prisoners. As a matter of justice they should be paid the same amount as free members of the community would be, but this would be coercive in a prison setting where alternative opportunities to make money are very few and pay badly. Clearly the payment should not be so large as to amount to undue influence, that is it must not obscure appreciation of the risk or weaken the will to self-preservation,⁶⁶⁴ but it is very difficult to draw a line between permissible and impermissible payment in this respect. Todd⁶⁶⁵ believes that payment may be coercive and exploitive not only in causing prisoners to enter a protocol, but in their continuing as research subjects, as it may cause them not to report adverse reactions because this would risk their dismissal from the project, with the consequence that such prisoners are exposed to excessive risk and the results distorted.

The problems, in summary, with respect to the voluntariness of prisoners’ consent, arise from deficiencies of living conditions and health care, arbitrary exercise of authority and restriction of communication⁶⁶⁶ and lack of opportunity to earn money or even to work. These deficiencies and the doubts they raise regarding consent can only be overcome by mandating that there shall be no medical experimentation on prisoners unless, *inter alia*, it is open to public scrutiny, grievance procedures are provided in the prison, the standard of living is raised to a basic minimum,⁶⁶⁷ an opportunity to work and earn money is provided and there are effective procedures ensuring that parole boards cannot take account of a prisoner’s

participation in research and that prisoners know this.⁶⁶⁸ Once this state of affairs is achieved some of the coercive effect of monetary payment is eliminated, but it must still not be so high as to constitute undue inducement, or so low that it means taking economic advantage of prisoners.⁶⁶⁹ One scheme is to pay additional money into a prisoners' fund used to augment the wages of all prisoners or for distribution to prisoners on release.

Such an approach recognizes that it is not possible to directly determine that a decision is the result of a free power of choice, rather this must be shown by the absence of unacceptable influences and interferences,⁶⁷⁰ which is the method of protection of prisoners adopted by both the "National Commission" and the D.H.E.W. in the United States.

Finally the requirements relating to therapeutic treatment of prisoners should be no different with respect to "informed" consent than with any other person, with the possible exception of when a disease state itself threatens other inmates. Here again it is necessary to clearly determine whether therapy is truly involved, or, especially in regard to psychological treatment, whether it is being used as a disguise for activities which should be classified as punishment.⁶⁷¹