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CHAPTER IV

Criminal Law Aspects of Consent to Medical Interventions

Before one can consider the effect of consent on the criminal law liability of doctors, or interpret and compare legislation or cases dealing with this in various jurisdictions, it is necessary to "set the legal scene" in each jurisdiction.

First, here in Canada, criminal law is a matter of federal jurisdiction governed by a *Criminal Code*, and hence for this purpose Quebec and Common Law Canada are one.[672] In the United States of America and in Australia criminal law is primarily a state matter, although the respective federal governments also have jurisdiction in criminal matters pertaining to the exercise of their constitutional powers,[673] which in Australia has been relied on to enact a *Federal Crimes Act*.[674] Some Australian states have a codified criminal law system and others rely on a common law basis, as modified by piece-meal legislation.[675] In the United States of America there is a *Model Penal Code* of the American Law Institute, the proposed official draft of which was published in 1962,[676] but at present, the substantive criminal law in that country is mostly in statutes, not infrequently in administrative regulations, sometimes in constitutions and sometimes found in the common law of crimes.[677]

England and France are unitary jurisdictions. English criminal law remains the uncodified common law,[678] but this is affected in various areas by specific statutory enactments.[679] In France the law is

codified in the *Code Pénal*, but the most significant distinction between this and any of the other jurisdictions, lies in the fact that an injured patient has an option whether to sue civilly or to intervene in a criminal action taken against the defendant, by becoming co-prosecutor with the "ministère public".[680] Further, the jurisprudence has established that the degree of fault which needs to be proved for liability in either regime is the same[681] and that the claimant can recover personal damages before a penal tribunal.[682]

The first point to be considered in discussing the effect of consent in criminal law, as applied in the medical context, is the legality or otherwise of any medical operation or procedure at Common Law or Civil Law. Various justifications for legality have been advanced and even legislated. In my view Sections 45 and 198 of the Canadian *Criminal Code*[683] have the combined effect of making surgical and medical treatment *prima facie* legally valid[684] in this jurisdiction, provided: the doctor has reasonable skill and knowledge, uses reasonable care, that it is reasonable to perform the operation, and it is for the benefit of the patient.[685] If this is the effect of these sections then it reverses the traditional Common Law presumption that such interventions are illegal and only justified on showing the following: consent; therapeutic benefit; that the operation is performed by a person with appropriate medical skills; and that there is lawful justification, an open-ended public policy requirement which is a means of prohibiting certain procedures.[686] Although the legal result flowing from either of these approaches is likely to be the same in many situations, this is not necessarily the case. Particularly in the area of human medical experimentation different attitudes may be engendered according to whether medical interventions are regarded as *prima facie* legally valid or invalid.

Now even assuming that all the necessary conditions are fulfilled in a therapy or therapeutic experimentation situation, the requirement of benefit needed under either of the above approaches is clearly lacking in non-therapeutic medical interventions, including research. However, from the fact that non-therapeutic experimentation takes place without criminal prosecutions being instituted,[687] and from *dicta* in some of the American incompetent organ donor cases,[688] and because court approval is not sought in the case of competent adult organ donors, an important likelihood emerges. In my view in the Common Law jurisdictions being examined, the law is being modified to accept, and the courts are using, consent and benefit as *alternative* justifications legalizing the medical intervention and not cumulative ones as traditionally required.

The same problem of justification of a medical intervention arises under French penal law and some authors argue that the lack of intention to harm and the positive aim to cure supplies this.[689] Levasseur makes the point that "[l]e médecin . . . échappe à toute poursuite sous la qualification de violences volontaires du moment qu'il a agi dans l'exercice *normal* de son activité professionnelle".[690] This raises the question, what is "abnormal" medical practice? It would seem that under French law non-therapeutic interventions would certainly be classified in the latter category, in which case the French penal law looks more to "l'act matériel d'intervention ou de traitement", rather than the motive of the doctor in acting, in order to characterize the intention accompanying the act as voluntary or not, for the purpose of imposing criminal liability.[691] Thus in France, the criminal liability of the doctor and the factors taken into account in seeing whether he was justified in acting as he did could vary simply according to the type of intervention he carried out, but certainly does not depend *prima facie* on the consent of the patient.

In fact Levasseur considers and rejects consent of the patient as a justification for a medical intervention as, he says, the better view is that the impunity of the doctor is based on an implicit authorization of the law—"l'ordre de la loi et le commandement de l'autorité légitime."[692] This means there is a general prohibition against violation of another's integrity, but the doctor's permission to do otherwise is an exceptional derogation from this. There are two inter-related factors underlying any such authorization of law, the significance of which it is necessary to consider more specifically within the context of criminal liability arising within the medical relationship. These factors are the nature and degree of the harm suffered, and the effect of consent in criminal law with respect to medical interventions.

First one should acknowledge that consent is certainly not a sole justification, and may be not even a justification for a medical act which could constitute a crime, although its presence may affect criminality. Then some crimes are only constituted by a certain degree of harm, for example, infliction of grievous bodily harm,[693] and others only where there is no operative consent, for example, assault.[694] All qualifications of rights or obligations protective of personal, physical or mental integrity are related to either the nature and degree of harm, or to the effective scope of consent and I suggest, are based on public policy considerations.[695] The criminal law is enacted primarily in the public interest, and comes into play when an act of one person against another threatens the community

itself in some way.[696] That is, the criminal law is a means of protecting society from acts of individuals which are harmful to it,[697] or acts contrary to the current morés.[698] Thus one can draw flexible and changeable limits which will mark off in any particular situation what is, or is not, criminal conduct. Clearly in many situations the answer is so obvious that it is not necessary to resort to such an analysis, but it is precisely in circumstances such as medical interventions including treatment and research, that this is useful.

Thus whether a certain degree of harm is acceptable and outside criminal liability, will depend on its nature and degree and the reasons for and circumstances under which it is inflicted. For example, in combat sport or medical treatment a certain degree of wounding may be acceptable, where it would not be otherwise, as this degree of harm inflicted for such a purpose in those circumstances is tolerable. Hence one has a ratio for determining acceptability, which I suggest means that below a certain insignificant degree of harm, the nature and purpose of the intervention can have very wide limits. However as the degree of harm increases, then the definition of what constitutes either a valid purpose, or an acceptable type or nature of harm, decreases in content so that in the instance of a life-threatening harm, for example, one arguably needs a therapeutic purpose if the attack is not to attract criminal liability.

Now it is necessary to consider how consent affects criminal liability. One often reads that consent is not a defence to a crime[699] and, in particular, that one cannot consent to death[700] or injury amounting to maim or mutilation[701] being inflicted upon oneself. I suggest that this is because the act is first classified as criminal, or non-criminal, according to the degree and nature of harm and the purposes and circumstances involved. If the act is assessed as criminal on this scale, then consent is irrelevant at least for criminal law purposes because, as Rubenstein says, "the prohibition is not directed against self-inflicted[702] injury; it is designed to prevent public desecration of one of the law's basic rules of behaviour. Beyond the concern for the physical well-being of the person, there lies the need to preserve the legal rule which prohibits one man from injuring another".[703]

If, on the other hand, without considering a consent factor, the act is classified as non-criminal initially, it may be that when one takes into account a lack of consent this will change the classification. It may so alter the nature and purpose of the act, that the ratio of degree and nature of harm present, *in the circumstances,* becomes

unacceptable and is designated criminal. Thus consent may affect the criminality of an act when the situation is such that the act would be non-criminal with consent, but criminal without it. Although one could give specific examples of such cases it is not possible to state a general rule any more definitely than this, as such a rule is not overt or express in the law. Rather it can be seen in operation, and I suggest is left in a flexible state, as it is based on public policy considerations which are open-ended and changing in content.

Now applying this rationale to the medical situation, it is possible to see that while some or all medical interventions may or may not give rise to potential criminal liability, there is a range from an intervention almost certain to do so, namely non-therapeutic experimentation causing some harm and done without consent, to an intervention certain not to, namely therapy causing minimal harm and carried out with consent. Similarly, such a range can be seen in the context of euthanasia, if the purpose of the medical act is treatment, necessary for instance to relieve pain and given with the consent of the patient, criminal liability is much less likely to be imposed than where ''active euthanasia'' is practiced.

While canvassing the subject of consent in the criminal law, one must also consider the effect, for criminal law purposes, of a child's or mental incompetent's consent, and of ''proxy'' consent. Firstly, consent within the criminal law is not ''informed'' consent. When consent is relevant, it is sufficient for the person to understand the nature of the act, and he does not necessarily have to understand its consequences.[704] Consequently, it is possible that a child is capable of giving effective consent at a younger age for purposes of criminal law, than for civil law purposes,[705] as in the latter situation effective consent depends on understanding at least some consequences. However, as the operative legal effect and scope of consent is limited in criminal law, in the sense of its being determinative in ''criminalizing'' or ''decriminalizing'' an act, this wider scope for recognizing a minor's consent will probably have little practical effect within the criminal law on the legality of medical interventions involving minors.

In relation to third party consent, I submit that all persons have the right to protection by the criminal law and that for reasons of policy the principle must be that no one else may waive this right. In other words, ''proxy'' consent should never be effective for criminal law purposes. Rather the approach taken should be that if the act was justified this should be established on the basis of implied consent, or

of a defence of necessity, which are generally recognized defences in criminal law. Although implied consent may be criticized as artifical and depends on substituting for the incompetent's judgment, just as "proxy" consent does theoretically, the rules governing the former are arguably different and, I submit, place a preferred emphasis on the rights of the incompetent rather than the power of the proxy consentor. How widely one defines the content of such defences, for instance whether the necessity must be the personal necessity of the incompetent, or may relate to the necessity of others, is once more a policy decision. But, again, it must be kept in mind that the criminal law's essential function is to be protective and that all persons have the right to its equal protection.

If the parents or a guardian have purported to consent to a criminal act on a child or incompetent, they may be guilty of criminal conspiracy, counselling, procuring or inciting a crime, or aiding and abetting a crime or a criminal.[706] One would need also to examine their possible criminal liability under any child abuse legislation applicable in the particular jurisdiction.[707] This could be applicable either by consent to, or perpetration of, or failing to report to the competent authorities, an act harming a child.[708]

Conclusion

Consent is a complex, general doctrine, functioning within both private and criminal law, and is fundamentally a legal mechanism for protecting autonomy and inviolability of the person within the limits to which these rights are recognized by the law.

The medical relationship is only one of a wide range of situations in which consent is relevant, but it crystallizes many of the most difficult problems faced in relation to consent. Firstly, what are the actual parameters of the limits set by the law in the relation to allowing one person to inflict physical or mental harm on another? How does one ensure that true consent is present, even with a "normal" competent adult, when, in the medical relationship, there is a situation which of necessity involves a power differential in relation to knowledge, emotional involvement and needs? And if this discrepancy is "artificially" aggravated by the condition in which the patient is placed, for instance a prison or institution, or even if he is particularly socially disadvantaged, what is the effect on consent? Finally, what happens when consent by the person concerned is impossible, and what does it mean if another gives "proxy" consent?

All of these questions require close and detailed analysis of the purposes sought in requiring consent, the legal and factual ways in which consent functions to serve these purposes, whether it is effective or not in achieving the desired aims and if not, or if consent is not possible, how the necessary aims may be achieved through other mechanisms. In all instances, rights, duties, powers, privileges, interests and immunities involved for of the patient, doctor and community are involved. Through private criminal law regulation particularly by defining the operation, scope and limits of consent, one seeks to balance these claims in acceptable harmony.

Finally, with the above generalizations in mind, as well as the necessity for fluidity and the possibility of continuing change which they import, I would like to summarize the major particular recommendations which have been made in this paper:

A. At a conceptual level:

1. That both criminal and civil law controls and remedies be retained in the area of consent to medical care.
2. That the rights to autonomy and inviolability be distinguished from each other and recognized.
3. That for the purposes of legal analysis and precedent, a distinction be made between the traditional doctrine of consent and the new doctrine of "informed" consent. The latter being wider will encompass the former, though the opposite proposition is not true.
4. That a distinction be made between the patient's consent to the medical contract and his consent to medical care.

B. At a practical level:

1. That the general rule should be that the patient's "informed" consent to all medical procedures must be obtained. This means that information about the nature of the proposed procedure and its attendant risks which a reasonable man in the patient's position would want to know, or which the doctor knows the particular patient would want to know, must be explained to the patient. In general the less necessary the procedure and the greater the risks, the more stringent is the content of the duty of disclosure. The doctor may reply on the patient's consent as being valid if there is apparent, subjective understanding of this information by the patient.
2. That the above general rule may be cut down in its operation by application of the doctrine of "therapeutic privilege". This means that in a particular case telling the patient some, or all, of the information required to be given under the general rule, would, *in itself*, harm him physically or mentally. It is not sufficient for operation of the privilege that the required disclosure would affect the patient's decision-making. Further, the privilege being an exception is to be construed narrowly, and being a justification the burden of proof of its applicability is on the person relying on it, namely the doctor.
3. That information be disclosed and consent obtained in as non-coercive a manner, language and situation as is possible. Except in very rare circumstances, deception is unacceptable. Further, there must be a constant concern to protect and be sensitive to the rights of privacy of the patient.
4. That both the necessity to inform the patient and to obtain his consent be seen as continuing requirements.

5. That it should be emphasized that the purpose of the doctrine of "informed" consent is protection of the patient.
6. That in life threatening situations when the patient refuses treatment, it is a policy decision as to whether the requirement for consent should be dispensed with by the law. In emergency situations where it is impossible to obtain consent a defence of necessity should apply.
7. That consent be regarded as a necessary, but not sufficient, justification for a medical intervention.
8. That consent to any significant medical intervention be obtained before a third party witness and be evidenced in writing.
9. That the coercion naturally present in the doctor-patient relationship, and especially the doctor-dying-patient relationship, be recognized.
10. That with respect to consent to medical interventions on children:
    (a) the "mature-minor" rule should be clearly established;
    (b) the term "proxy consent" should be abandoned and replaced by either parental authorization or permission;
    (c) the parent may consent to therapy on the child not yet within the scope of the "mature-minor" rule. The child should have a right of objection or veto, but this may, be overridden by the parent with justification;
    (d) except in extremely rare circumstances a parent may not consent to non-therapeutic, or more than minimal risk personally non-beneficial interventions on the child;
    (e) special protection must be given to institutionalized children with respect to consent to medical interventions on them.
11. That with respect to consent to medical interventions on foetuses:
    (a) where therapy is involved the same rules apply as for non-discerning children;
    (b) where the intervention is non-therapeutic for the foetus but directed at therapy for the mother the mother's consent is adequate;
    (c) in all other cases any rules on consent should recognize the mother's, and possibly a medical research physician's, conflict of interest.
12. That with respect to consent to medical interventions on mental incompetents:
    (a) their consent should be sought to the extent that they are capable of giving it;

(b) in cases where the mental incompetent is factually incapable of consenting the same rules should apply as suggested for non-discerning children, including institutionalized children.

13. That with respect to medical interventions on prisoners:
    (a) the prisoners' "informed" consent to all medical treatment must be sought. The only exception to treating a prisoner without consent is where he has a disease state threatening the health or well-being of other prisoners;
    (b) a very high degrec of care must be taken to counteract the coercive effects on consent, of the institutionalization and deprivation suffered by prisoners.

Endnotes

1. *British North American Act* 1867, 30-31 Victoria, c. 3.

2. J.S. Mill, "Utilitarianism, On Liberty, and Considerations on Representative Government", London; J.M. Dent & Sons Ltd., 1972, in "On Liberty", at pp. 71-72.

3. P. Devlin, "The Enforcement of Morals", London, Oxford University Press, 1965. Extracts reprinted in J. Katz ed., "Experimentation with Human Beings", New York; Russell Sage Foundation, 1972 (hereafter referred to as "Katz ed.") at pp. 541-4.

4. For example, E.D. Pellegrino "Editorial: Protection of Patient's Rights and the Doctor-Patient Relationship", Prev. Med. 4(4)398 (1975), at p. 399.

5. See L. Loevinger, "Jurimetrics: Science in Law" in W.A. Thomas, ed., "Scientists in the Legal System. Tolerated Meddlers or Essential Contributors?", Michigan; Ann Arbor Science Publishers Inc., 1974, (hereafter referred to as "Thomas ed.") p. 7.

6. P.A. Freund, "Legal Frameworks for Human Experimentation", in P. Freund ed., "Experimentation with Human Subjects" New York, George Brazilier, 1970, (hereafter referred to as "Freund ed."), p. 105, at p. 106.

7. *Ibid.* The qualification being that the law must balance the individual's right of free choice and self assertion, with solicitude for his or her integrity.

8. A.M. Capron, "Informed Consent in Catastrophic Disease Research and Treatment", (1974-75) 123 University of Pennsylvania Law Revue 340, at p. 428.

9. C. Fried, "Medical Experimentation: Personal Integrity and Social Policy", Amsterdam and Oxford; North Holland Publishing Co., 1974, at p. 97.

10. See, for example, R.C. Fox, "Some Social and Cultural Factors in American Society Conducive to Medical Research on Human Subjects", reprinted in I. Ladimer and R.W. Newman, eds., "Clinical Investigation in Medicine: Legal ethical and Moral Aspects", Boston; Law-Medicine Research Institute, Boston Univ., 1963 (hereafter referred to as "Ladimer and Newman eds.") p. 81, at p. 107.

11. A. Decocq, "Essai d'une théorie générale des droits sur la personne", Paris; Librairie Générale de Droit et de Jurisprudence, R. Pichon et R. Durand, Auzias, 1960, at No. 12.

12. L. Kornprobst, "Responsabilités du médecin devant la loi et la jurisprudence française", Paris; Flammarion, 1957, at p. 254.

13. E. Nizsalovszky, "A Legal Approach to Extraordinary Medical Actions", Budapest; Akadémiaikiado, 1974, at p. 45 *et seq*.

14. This is to ask whether or not rights in general are in themselves autonomous, that is self-determining, which is really to make the distinction between the "natural law school" who regard rights as existing independently of human volition, and "the positivists" who do not. Thus autonomy may be looked at as an autonomous right affecting the autonomy of persons.

15. 211 N.Y. 127 at p. 129; 105 N.E. 92 at p. 93 (1914).

16. W.L. Prosser, "Handbook of the Law of Torts", 4 ed., Minnesota; West Publishing Co., 1971, at p. 101.

17. P.D.G. Skegg, "A Justification for Medical Procedures Performed without Consent", (1974) 90 Law Quarterly Review 512, at p. 514.

18. For example, see B. Starkman, "Preliminary Study on Control of Life", unpublished paper presented to the Law Reform Commission of Canada, 1974, who lists cases involving blood transfusions given to non-consenting adults, in the United States.

    I. Kennedy, "The Legal Effect of Requests by the Terminally Ill and Aged Not to Receive Further Treatment from Doctors", [1976] Criminal Law Review 217, who says that the right to self-determination in medical treatment situations, when this means refusing medical care, "is confined within narrow . . . ill-defined bounds" (at p. 218).

19. R.G. Spece, "Notes: 'Conditioning and Other Technologies Used to Treat?' 'Rehabilitate?' 'Demolish?' Prisoners and Mental Patients", (1972) 45 Southern California Law Review 616, at p. 675.

20. This is an interestingly stated view in that it means that one has a primary right *against* treatment together with the power to waive this and, presumably, another *separate* right *to* treatment. This distinction raises the consideration of whether these rights may be based on, or governed by, different value principles.

21. J.G. Fleming, "The Law of Torts", 4th ed., Australia; The Law Book Co. Ltd., 1971.

22. *Ibid*., at p. 80. This statement may be supported by reference to *Marshall v. Curry* [1933] 3 DLR 260 where Chief Justice Chisholm states that in "a great emergency which could not be anticipated . . . it is the surgeon's duty to act in order to save the life or preserve the health of the patient". In arriving at this conclusion the Judge found two Civil Law cases from Quebec, *Parnell v. Springle* (1899) 5 Rev. de Jur. 74, and *Caron v. Gagnon* (1930) 68 Que. S.C. 155, persuasive (at pp. 272-275). He stated that the "jurisprudence established in the Province of Quebec [in this respect] . . . can well be adopted in other jurisdictions" (at p. 275). This is interesting from the point of view of whether the Common Law and Civil Law have different attitudes to the relative values of autonomy and inviolability (see *infra*, pp. 8-10, with respect to the latter) as it assumes, at least in the circumstances of this case, where there is an unanticipated medical emergency and the patient is unable to consent, that they do not.

23. J.G. Fleming, "Law of Torts" 5th ed. Australia; Law Book Co., 1977, at p. 81, states that " . . . the balance between preservation of life and self-determination is found in authorizing [a] medical procedure only when it would be unreasonable, not just inconvenient to postpone until consent could be sought. Justification for this is found not in fictitiously imputing to the patient a consent he has obviously not given, but in the humanitarian duty of the medical profession."

24. See *infra*, pp. 8-9.

25. One may dispose of the legal problems raised in relation to autonomy in such a situation, that is it may still be honoured legally in form, if not in substance, by the devices of either implied consent, or a doctrine of necessity. See P.D.G. Skegg, *supra*, note 117.

    Note also that in *Marshall v. Curry*, cited *supra*, note 22, the Court expressly rejected "resorting to a fiction . . . [of implied] consent".

26. J.G. Fleming, *op. cit.*, note 21, at p. 81, footnote 1.

27. J.G. Fleming, *op. cit.*, note 23, at p. 81

    It is interesting to note these changes between the two editions of this text, as they reflect the uncertain situation of the law. Although both statements are carefully "hedged" they start from opposite propositions of what a Court *may* hold.

28. See I. Kennedy, *supra*, note 18, for an interesting discussion and actual case presentation of the factual and theoretical issues involved in deciding which of these two principles is to be given precedence.

    See also S.H. Imbus and B.E. Zawacki, "Autonomy for Burned Patients When Survival is Unprecedented", NEJM 297(6) 308 (1977).

    For comment on this latter article see E.J. Cassell, "Editorial: Autonomy and Ethics in Action", NEJM 297(6) 333 (1977). Note also that this conflict is at its sharpest in the euthanasia debate.

29. L. Komprobst, *op. cit.*, note 12, at p. 254

30. See *infra*, p. 11, *et seq*.

31. See *supra*, p. 3, and note 2.

32. See *supra*, p. 6, and note 29.

33. This attitude may reflect the Common Law's tradition of strict distinction, when imposing liability or duty, between omission and commission, or nonfeasance and misfeasance. In the former cases, respectively, the Common Law only exceptionally intervenes.

34. See *infra*, p. 43, *et seq*.

35. This legislation was enacted on 23rd Dec. 1976. For a report on it see, "The French Solution: Removing Cadaver Organs Without Family's Permission", The Hastings Center Report 7(3) 2 (1977).

36. For example see P.J. Doll, "Les problèmes juridiques posés par les prélèvements et les greffes d'organes en l'état actuel de la législation française", J.C.P. 1.D. 2168. R. Savatier, "Les problèmes juridiques des transplantations d'organes humains", J.C.P. 1969.1.2247.

This justification, I suggest, did not widen the right to consent, it merely allowed a defence, or estoppel (fin de non reçevoir), to operate for the purpose of determining legal liability.

37. See *infra*, p. 43, *et seq.*, for a discussion of the limits to the right of consent.

38. See C.R. Burns & H.T. Engelhardt, "Introduction to a Symposium", Texas Reports on Biology and Medicine 32(1) p. ix, (1974), who express the same idea.

39. P.L. Bereano, "Courts as Institutions for Assessing Technology", in "Thomas ed." *op. cit.*, note 5, p. 73, at p. 77.

40. *Supra*, pp. 5-6 and pp. 8-9.

41. P. Laget, "Expérimentation et médecine", in "Le médecin face aux risques et à la responsabilité", textes recueillis par M. Eck, Paris; Fayard, 1968 (hereafter referred to as "Eck ed.") p. 301, at p. 311.

42. H. Jonas, "Philosophical Reflections on Experimenting with Human Subjects", in "Freund ed.", *op. cit.*, note 6, p. 1, at p. 3.

43. A. Mayrand, "L'inviolabilité de la personne humaine", Montréal; Wilson and Lafleur Ltée., 1975, at No. 3.

44. A. Decocq, *op. cit.*, note 11, at No. 12.

45. *Ibid.*

See also Nos. 516 and 517.

46. A. Mayrand, *op. cit.*, note 43, at No. 40.

47. R. & J. Savatier, J.M. Auby & H. Péquignot, "Traité de Droit Médical", Paris; Librairies Techniques, 1956, at No. 247.

48. R. Nerson, "L'influence de la biologie et de la médecine moderne sur le droit civil", (1970) 68 Revue Trimestrielle de Droit Civil, 661.

49. *Ibid.*, p. 672.

50. *Ibid.*

51. *Ibid.*, p. 676.

52. *Ibid.*, p. 675.

52a. Note that unless otherwise stated, or unless the contrary is clear from the context, the term " 'informed' consent" is used in a generic sense as covering all necessary aspects of consent, that is those of competency and voluntariness as well as that of adequate information.

53. For a discussion of fiduciary duty in the medical relationship see: *Radcliffe v. Price* (1902) 18 T.L.R. 466; *Re C.H.G.* [1970] Ch. 574; [1970] 2 All ER 740; *Kenny v. Lockwood*, cited *supra*, note 62; *Hunter v. Brown* 4 Wash. App. 899; 484 P. 2d 1162 (1971); *Dow v. Kaiser Foundation* 12 Cal. App. 3d. 488; 90 Cal. Rpt. 747 (1970); *Natanson v. Kline* 354 P. 2d 670; 350 P. 2d 1093 (Sup. Ct. Kans. 1960); especially Schroeder, J., at p. 1101.

54. See: *R. v. Clarence* (1888) 220 B.D. 23; J.G. Fleming, *op. cit.*, note 23, at pp. 78-79; A. Roddey Holder, "Medical Malpractice Law", New York; John Wiley & Sons, 1975, at pp. 227-8.

See also *infra*, p. 37.

55. This is one example of how the fiduciary duties of a doctor can be super-imposed on other duties, to establish a more satisfactory range and intensity of duties of physicians, with the fiduciary relationship serving as a basis and justification for imposing such obligations. Thus it shows the importance of the Law strongly recognizing and adopting such a fiduciary relationship in situations of doctor-patient interaction.

56. See, for example, G. Boyer Chammard and P. Monzein, "La responsabilité médicale", Paris; Presses Universitaires de France, 1974, at pp. 138-147 and at p. 236, where these authors cite two *Cour de Cassation* cases (one of these being Cass. 27 janvier 1970, B. Civ. 1970.1, No. 37, 30) which state that in the aesthetic surgery situation there is a very stringent duty on the doctor to inform the patient of all risks; A.R. Holder, *op. cit.*, note 54, at pp. 227-8.

57. See *infra*, p. 28 *et seq*.

58. See A.M. Capron, *supra*, note 8, at pp. 367-9.

59. For example, see J. Katz, "The Education of the Physician Investigator", in "Freund, ed." *op. cit.*, note 6, p. 293, at p. 306.

60. Also note that the Ontario High Court has recently twice specifically expressed this as the purpose of requiring "informed" consent, in *Kelly v. Hazlett* (1977) 75 D.L.R. 3d. 536 at p. 556; and; *Reibl v. Hughes* (1977) 78 D.L.R. 3d. 35, at p. 41.

61. See *supra*, pp. 5-6.

62. For discussion of the doctrine of "therapeutic privilege" see; E.D. Pellegrino, *supra*, note 4, at p. 339; B. Dickens, "Information for Consent in Human Experimentation", (1974) 24 University of Toronto Law Journal, 381 at p. 395; G. Boyer Chammard and P. Monzein, *op. cit.*, note 56, at pp. 134, 138-147, 150 and 236; X. Ryckmans and R. Meert-van de Put, "Les Droits et les Obligations des médecins", 2 éd., Tomes I & II, Brusselles; Maison Ferdinand Larcier, S.A. 1971, at T. 1, Nos. 570-3; L. Kornprobst and S. Delphin, "Le Contrat de soins médicaux", Paris; Sirey, 1960, at No. 208; C. Fried, *op. cit.*, note 9, at p. 21; H.W. Smith, "Therapeutic Privilege to Withhold Specific Diagnosis from Patient Sick with Serious or Fatal Illness", (1946) 19 Tennessee Law Review 349. Reprinted in part in "Katz ed.", *op. cit.*, note 3, at p. 677; N. Rice, "Informed Consent: The Illusion of Patient Choice", (1974) 23 Emory Law Journal 503 at p. 506; J. Fletcher, "Human Experimentation: Ethics in the Consent Situation", (1967) 32 Law and Contemporary Problems 620, at p. 640, who advocates some "mediate" rule for withholding information — perhaps telling a relative of the patient or a "physician friend". The adoption of such an approach by a court, is discussed by A. Meisel, "The Expansion of Liability for Medical Accidents: From Negligence to Strict Liability by Way of Informed Consent", (1977) 56 Nebraska Law Rev. 1:51, at p. 101, f.n. 147. For an excellent discussion of "therapeutic privilege" in American law, including problems of who bears the burden of proving or disproving the operation of the privilege, and the standard applicable to judge whether information may be withheld, see

pp. 99-107 of this article; A.M. Capron, "Experimentation and Human Genetics: Problems of 'Consent'" in A. Milunsky and G.J. Annas eds., "Genetics and the Law", New York; Plenum Press, 1976 (hereafter referred to as "Milunsky and Annas eds.") p. 319, at p. 322; H.L. Blumgart, "The Medical Framework for Viewing the Problem of Human Experimentation", in Freund ed., *op. cit.*, note 6, p. 39, at p. 48; R. Boucher *et al*, "La responsabilité hospitalière", (1974) 14 Cahiers de Droit 2:219, at p. 473; P.S. Cassidy, "Cooper & Roberts: A 'Reasonable Patient' Test for Informed Consent", (1973) 34 University of Pittsburgh Law Rev. 500, at pp. 505-6, reviews the United States cases which discussed therapeutic privilege.

"Notes: Restructuring Informed Consent, Legal Therapy for the Doctor-Patient Relationship", (1970) Yale Law Journal, 1532, at pp. 1566-7, where a suggestion for restructuring therapeutic privilege is made; *Male v. Hopmans* (1965) 54 D.L.R. 2d 592; affd. 64 D.L.R. 2d. 105; *Johnston v. Wellesley Hospital* (1970) 17 D.L.R. 3d. 139; *Kenny v. Lockwood* [1932] 1 D.L.R. 507; *Salgo v. Leland Stanford Junior University Board Trustees* 317 P. 2d. 170 (Cal. 1957); *Cobbs v. Grant* 502 P. 2d. 1; 104 Cal. Rptr. 505 (1972); *Canterbury v. Spence* 464 F. 2d. 772 (C.A. Dist. of Col. 1972); *Wilkinson v. Vesey* 295 A. 2d. 676 (1972).

63. Note that the non-application of therapeutic privilege to the non-therapeutic situation is stated by a court in; *Halushka v. University of Saskatchewan* (1965) 53 D.L.R. 2d. 436; and in; *Hyman v. Jewish Chronic Diseases Hospital* 206 N.E. 2d 338 (1965).

See also N. Hershey & R.D. Miller, "Human Experimentation and the Law", Germantown, Maryland; Aspens Systems Corporation, 1976, at p. 35; W.J. Curran, "Governmental Regulation of the Use of Human Subjects in Medical Research: The Approach of Two Federal Agencies", in "Freund ed.", *op. cit.*, note 6, p. 402, at p. 426 *et seq.*, who discusses the United States F.D.A. Regulations governing the experimental use of drugs and the consent required in such situations (see *infra*, note 80) which show "therapeutic privilege" applies, if at all, only in the therapeutic situation.

For further discussion of these regulations in this respect see; M.J. Bloom, "Non-therapeutic Medical Research involving Human Subjects", (1973) 24 Syracuse L. Review 1067, at p. 1080-81; M.F. Ratnoff, "Who Shall Decide When Doctors Disagree? A Review of the Legal Development of Informed Consent and the Implications of Proposed Law Review of Human Experimentation", (1975) 25 Case Western Reserve Law Review 472, at p. 504 *et seq.*; W.J. Curran & E.D. Shapiro, "Law Medicine and Forensic Science", 2 ed., Boston, Little Brown & Co., 1970, at p. 595 *et seq.*; G.J. Annas, L.H. Glantz and B.F. Katz, "Informed Consent to Human Experimentation: The Subject's Dilemma", Cambridge, Massachusetts; Ballinger Publishing Co., 1977, at p. 7.

64. 95 Eng. Rep. 860; 2 Wils, K.B. 362 (1767).

65. The Nuremberg Code was developed by the prosecution in the Nazi War Crimes Case *United States v. Karl Brandt et al.*, Trials of War Criminals Before Nuremberg Military Tribunals Under Control Council Law No. 10 (Oct. 1946 — April 1949) The Medical Case, Washington's United States Government Printing Office, 1947. It is reprinted in W.J. Curran and E.D. Shapiro, *op. cit.*, note 62, at p. 888.

66. Medical Research Council Annual Report for 1962-3. Cmnd. 2382, Her Majesty's Stationery Office, London, 1964. Also reprinted in fall B.H.J. 1964.2.178.

67. Royal College of Physicians (England), Report of the "Committee on the Ethics of Clinical Research Investigations in Institutions", July 1973.

68. "AMA Ethical Guidelines for Clinical Investigation", Adopted by House of Delegates, American Medical Association, Nov. 30, 1966, Chicago; American Medical Association.

69. "Declarations of Helsinki. Recommendations guiding medical doctors in biomedical research involving human subjects". Adopted by the 18th World Medical Assembly, Helsinki, Finland, 1969. As Revised by the 29th World Medical Assembly, Tokyo, Japan, 1975. Published by the World Medical Association, 01210 Ferney-Voltaire, France.

69a. Medical Research Council, "Ethical Considerations in Research Involving Human Subjects", Report No. 6, Ottawa; Supply and Services, 1978, (hereafter referred to as "Ethics in Human Experimentation") at p. 21.

70. 21 C.F.R. § 312.1.

71. Fed. Reg. March 13, 1975; 40 F.R. 50 11854-5 45 C.F.R. § 46.3(c).

72. *Décret du 14 janvier 1974*. Extracts published in La Nouvelle Presse Médicale 3(5) 265 (1974), at p. 266. Published in full in "La responsabilité civile des médecins", V^e^. Colloque de Droit Européen organisé par la collaboration des Universités "Jean Moulin" et "Claude Bernard", Lyon 3-5 juin, 1975.

    This duty is limited by Article 34 *Code de Déontologie médicale* (France) Décret No. 55-1591 du 28 novembre 1955, portant *Code de Déontologie médicale* et remplaçant le règlement d'administration publique no. 47-1169 en date du 25 juin 1947, which states "Un pronostic grave peut légitimement être dissimulé au malade. Un pronostic fatal ne peut lui être révélé qu'avec la plus grande circonspection, mais il doit l'être généralement à sa famille, à moins que le malade ait préalablement interdit cette révélation ou désigné les tiers auxquels elle doit être faite".

    Cf. Code of Medical Ethics of the Professional Corporation of Physicians of Quebec, second edition (2nd Reprint), June, 1976. Ratified by Decree no. 3391, Oct. 6, 1971, which establishes a general duty not to conceal a serious or fatal diagnosis from a patient requesting its disclosure except with justifiable reasons. This duty is retained in the Draft Regulation *Professional Code* 1973 c. 43 Gazette Officielle du Québec, 31 août 1977, 109^e^ année, No. 34, 4243-4255 at 4247, 2.03.30.

73. *Cf.* Plato's doctor in the "Laws" who obtains "informed" consent — referred to A. Buisson, "Human Experimentation through the Ages", in D.P. Flood, ed., "Medical Experimentation on Man", A Cahier Laenac, Trans. M. Gerrard Carroll, Chicago; Henry Regnery Co., 1955, (hereafter referred to as "Flood ed."), at p. 14.

74. G. Edgar, "Commentaire du Code de morale pour les hôpitaux", Montréal; Wilson & Lafleur, 1957, at p. 34.

This same approach was recently advocated by the American Surgical Association, "American Surgical Association Statement on Professional Liability, September, 1976", NEJM 295(23) 1293 (1976), who want to modify the requirements of "informed" consent in the United States, so that it is only necessary for the doctor to explain at the patient's request.

75. R. Boucher et al., *supra*, note 62, at p. 474.

76. [1974] C.S. 105. Cited *ibid*., f.ns. 181 & 185.

77. G. Boyer Chammard & P. Monzein, *op. cit*., note 56, at p. 133.

78. This view may be supported by reference to: C. Blomquist, "A New Era in European Medical Ethics", The Hastings Center Report 6(2) 7 (1976); P. Lombard, P. Macaigne and B. Ondin, "Le médecin devant ses juges", Paris; editions Robert Laffont, 1973, at p. 122 & p. 167 who say American jurisprudence is even now more exacting than the French, on the duty to inform the patient; R.C. Fox, *supra*, note 10, at p. 99, who suggests that more information is given to patients by United States doctors than European ones, because the public in the United States are made more aware of medicine through their mass media.

Although I have spoken generally of the duty to inform the patient in the Common Law, the above authors refer specifically to American Common Law and certainly this shows the longest and strongest development of this trend, although it is present in other Common Law jurisdictions. There are two aspects of this trend, the development of a duty to inform and the development of its required content. It is particularly in the latter aspect that most Common Law jurisdictions trail the American ones. For example, see the statement of W.F. Bowker "Experimentation on Humans and Gifts of Tissue: Articles 20-23 of the Civil Code", (1973) 19 McGill Law Journal 2:161, who, after analyzing the case-law concludes that in Canada physicians "have a wide scope in exercising their judgment" in informing their patients (at p. 169). Note that the author expressly states that this discretion does not extend to non-therapeutic experimentation, citing *Halushka v. University of Saskatchewan*, cited *supra*, note 63, as authority, and would be of doubtful validity except in extreme circumstances in therapeutic experimentation.

79. See *Pedesky v. Blaiberg* 59 Cal. Rpt. 294 (Cal. 1967), for a statement by a Common Law court that a doctor has a duty to ensure the patient understands the information given.

In a Civil Law jurisdiction R. Boucher *et al*, *supra*, note 62, at p. 474, referring to Quebec, say the obligation to inform the patient is one of result "en ce sens que les renseignements donnés devraient avoir pour effet de permettre au patient de donner un consentement libre et éclairé . . . [L]e médecin . . . se devra de donner tous les renseignements nécessaires, toutes les explications suffisantes pour que le patient puisse *comprendre* la portée de l'acte auquel il consent". (Emphasis added). L. Walters, "Some Ethical Issues in Research Involving Human Subjects", Perspectives in Biology and Medicine 20(2) 193 (1977), at p. 205, says that in the research context the choice of a "reasonable patient" standard — that is use of objective criteria to determine both the scope of disclosure and the patient's understanding — or a "subject's need" standard — employing subjective criteria for these purposes — "will significantly affect the stringency of the disclosure requirement".

80. See Medical Research Council, "Ethics in Human Experimentation", *supra*, note 69(a), at p. 21, which requires that "[a] subject has given a proper consent . . . on the basis of well understood . . . information . . . "; J.C. Garham, "Some observations on informed consent in non-therapeutic research" J. Med. Ethics 1(3) 138 (1975); A.M. Capron, "Informed Consent in Catastrophic Disease Research and Treatment", (1974-75) 123 University of Pennsylvania Law Review 340, at p. 413; R. Boucher *et al*, *supra*, note 62; W.G. Todd, "Non-Therapeutic Prison Research: An analysis of Potential Legal Remedies", 1975 Albany Law Review, 799, at p. 810, f.n. 91, citing *Knecht v. Gillman*, 488 F. 2d. 1136 (8th Circ. 1973), as authority for requiring subjective comprehension for "informed" consent; X. Ryckmans and R. Meert-van de Put, *op. cit.*, note 62, at No. 571; N. Hershey and R.D. Miller, *op, cit.*, note 63, at p. 64, in relation to consent to medical research, suggest that an ethical review board should require one of two alternative conditions to be fulfilled before approving research: that the subject understands *or* the subject rejected an offer of information; *Cf.* D.H.E.W. Regulations, Fed. Reg. 23 Aug. 1974, at 30649, which expressly state that to require assurance that the subject comprehends the disclosure "goes beyond requirements for informed consent as they have generally been articulated by the courts". This statement, in turn, must be compared with the definition of "informed consent" in these Regulations (45 CFR § 46.3) which is defined as meaning "knowing consent". Presumably, therefore, the Secretary of D.H.E.W. in the former comment is referring to the Regulations not requiring *assurances* of comprehension, rather than their not requiring *comprehension* by the subject to exist in fact.

The Nuremberg Code, *supra*, note 65, at parag. 1, requires that the person "should have *sufficient knowledge* and *comprehension* . . . to make an *understanding* and enlightened decision". (Emphasis added.)

Cf. The Declaration of Helsinki, *supra*, note 69, at I Basic Principles, parag. 9, which is silent beyond requiring that "each potential subject be *adequately* informed . . . " and his "informed consent" obtained.

The United States F.D.A. Regulations, at 21 C.F.R. § 310.102(h), require that the patient be given information "as to enable him to make a decision on his willingness to receive [an] investigational drug . . . [which] means that before the acceptance of an affirmative decision by such person the investigator should . . . tak[e] into consideration such person's . . . ability to *understand* . . . " the information of which disclosure is required.

The National Health and Medical Research Council, "N.H.M.R.C. (Aust.) Statement on Human Experimentation", Reprinted in The Medical Journal of Australia, 1966 (2) 325, requires *comprehension* of the nature of an experiment by the subject or his guardian; J.R. Waltz and T.W. Scheuneman, "Informed Consent to Therapy", (1969) 64 Northwestern Univ. Law Rev. 628. Reprinted in part in "Katz ed.", *op. cit.*, note 3, p. 579 *et seq.* and p. 605 *et seq.*, at p. 580, say the duty is to inform so that a reasonable man (doctor) would think the patient understood, but this is not an absolute duty to ensure the patient understood.

81. Cited *supra*, note 60.

82. Cited *supra*, note 60.

83. *Kelly v. Hazlett*, cited *supra*, note 60, at pp. 563-4.

84. Reibl v. Hughes, cited *supra*, note 60, at p. 41. (Emphasis added).

85. *Ibid*., p. 44. (Emphasis added).

86. J.C. Garham, *supra*, note 80, carried out an experiment on obtaining informed consent and concluded that despite all efforts to achieve this end, it was only accomplished in five out of forty-one cases in which it was attempted.

    See also James Reed "Knowledge, Power, Man & Justice: Ethical Problems in Biomedical Research", Can. J. Genet. Cytol. 17:297 (1975), at p. 300, who states that with the increasing complexity of modern medical technology, it will become more difficult for even the educated layman to understand the impact of what he is told.

87. A. Meisel, *supra*, note 62, at p. 117, makes the observation that if the function of "informed" consent is to safeguard the individual's right to self-determination, even his right to make "foolish" decisions, then the proper emphasis is exclusively on the information disclosed by the physician. If however the function is to *assure* rational decision-making, then one must also focus concern on the patient's comprehension of what is disclosed. I submit that at least in non-therapeutic situations, "informed" consent should serve both functions.

88. A.M. Capron, *supra*, note 8, at p. 414.

89. See for example *Natanson v. Kline*, cited *supra*, note 53, at p. 465.

90. G. Boyer Chammard & P. Monzein, *op. cit*., note 56, at p. 150; L. Kornprobst & S. Delphin, *op. cit*., note 62, at No. 208.

    Royal College Physicians (England), "Code Ethics", *supra*, note 67, at p. 2, requires that physicians do not seek consent to "beneficial research" where it is inappropriate or inhumane to do so.

    Cobbs v. Grant, cited *supra*, note 62, at 502, P. 2d., 12; 104 Cal. Rptr., 516, where the privilege was suggested as operating where "the disclosure would have so seriously upset the patient that the patient would not have been able to dispassionately weigh the risks of refusing to undergo the recommended treatment".

    Note that this statement must be distinguished from a case in which the information does not appear likely to "so seriously upset the patient", but may have the effect of causing him to refuse treatment. This is the patient's privilege and in such cases the justification of "therapeutic privilege" does not operate.

91. See, for example, B. Dickens *supra*, note 62, at p. 400. This author does, however, seem to suggest that "public interest" may justify withholding a narrow category of information in some circumstances. To the extent that this is true I respectfully disagree with it, unless what is meant is that the risks envisaged need not be disclosed because they are irrelevant or immaterial, as even if one considers it valid to conscript experimental subjects, I believe they still have a right to know the full extent of that for which they are being conscripted. To do otherwise is not only to use people, but to do so deceptively. It is less contradictory of their rights to use them openly, even if this is contrary to their wills.

92. See A.R. Holder, *op. cit.*, note 54, at p. 226, who cites a list of cases supporting the view that when new or experimental treatment is involved, there is at least a duty to warn that all effects are not known. That is, to this extent at a minimum, a "therapeutic privilege" does not apply to even therapeutic research and possibly not to some "new" therapy.

93. See J.R. Mason, "*Kaimowitz v. Department of Mental Health*: A Right to be Free from Experimental Psychosurgery", (1974) 54 Boston University Law Review 301, at p. 317; J.R. Waltz, "The Liability of Physicians and Associated Personnel for Malpractice in Genetic Screening", in "Milunsky and Annas, eds.", *op. cit.*, note 62, at p. 148; C. Fried, *op. cit.*, note 9, at p. 20.

Davies v. Wyeth Laboratory Inc. 399 F. 2d.(9th Circ. 1968), where a one in a million chance of contracting polio from a vaccine used to immunize the patient was held to be a material fact which should have been disclosed.

See *Canterbury v. Spence*, cited *supra*, note 62, at pp. 786-7.

Wilkinson v. Vesey, cited *supra*, note 62, at p. 689, for a definition of a material risk, which is when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to undergo the proposed therapy.

94. B. Dickens, *supra*, note 62, at p. 395; G. Edsall, "A Positive Approach to the Problem of Human Experimentation", in "Freund ed.", *op. cit.*, note 6, p. 276, at p. 281. Refers to the unreported proceedings against the two doctors involved in the "cancer-cell case" (the injection of live cancer cells into geriatric patients for experimental purposes, which gave rise to *Hyman v. Jewish Chronic Diseases Hospital*, cited *supra*, note 63) before the New York Board of Regents, the pertinent medical licensing authority, which suspended the licences of the two physicians with a stay of implementation, on the ground *inter alia* that the physicians had no right to withhold any of the facts that the volunteer might have regarded as *revelant*.

"Notes: Yale L.J.", *supra*, note 62, at pp. 1559-60.

95. G. Edsall, *ibid.*, says the individual patient or research subject must "be given full opportunity to exercise *his own judgment*" which implies a subjective standard if such opportunity is to be as "full" as possible; A. Meisel, *supra*, note 62, at p. 109 and f.n. 165, states that many commentators "have assumed the subjective test applied". He is speaking here of a subjective or objective test of causation of injury by the non-disclosure. In other words, whether the test is, would this particular patient (a subjective test), or would a reasonable patient (an objective test), on the balance of probabilities, have changed his decision if the required disclosure had been made. As a matter of logical consistency, the same test as that used to determine causation must be applied at the time of disclosure to determine what must be disclosed, although it is being used one step in advance at the stage of disclosure. Thus on this line of argument, a subjective test, from the patient's point of view, would be used to determine the content of the required disclosure if a subjective test of causation is used.

96. *Halushka v. University of Saskatchewan*, cited *supra*, note 63.

Canterbury v. Spence, cited *supra*, note 62, at pp. 790-1.

Cobbs v. Grant, cited *supra*, note 62, at 502 P. 2d. p. 11; 104 Cal. Rptr. p. 515; J.R. Mason, *supra*, note 92, at p. 317.

"Notes: Yale L.J.", *supra*, note 62, at pp. 1559-60; J.R. Waltz and T.W. Scheuneman, *supra*, note 80, at p. 640; "Katz ed.", at p. 580.

97. Cited *supra*, note 62.

See also *Wilkinson v. Vesey*, cited *supra*, note 62.

Cf. Karp v. Cooley and Liotta, 349 F. Supp. 827 (S.D. Tex. 1972), 493 2d. 408 (Fed. Ct. of Apps. 1974), where the standard of disclosure was set by the court on the basis of what a reasonable doctor would disclose. It may be that a Harvard Law Review case note, "Physician's Duty to Warn. *Di Fillipo v. Preston* (Del. 1961)" (1962) 75 Harv. L.R., 1445, was seminal in this change to a "lay standard" by the courts in the United States. This "note" argued that the duty to warn should be based on the patient's needs and not on medical practice; J.A. Robertson, "Compensating Injured Research Subjects II The Law", The Hastings Center Report 6(6) 29 (1976) at p. 31, says about one quarter of the states in the United States follow *Canterbury v. Spence* (*ibid.*).

98. Cited *supra*, note 60.

99. *Ibid.*, p. 558.

100. *Ibid.*, p. 565.

101. *Ibid.*

102. *Ibid.*

103. It is not clear if a subjective or objective test applies in relation to disclosure of risks relevant to a cause of action in assult and battery, but it is probably objective, that is risks which a reasonable patient would consider to be "basic to the nature and character of the operation", (*Kelly v. Hazlett ibid.*, p. 558) must be disclosed. Although such a test, based on the reasonable patient, was expressly rejected in relation to the negligence standard (*ibid.*, p. 565) this, or the more onerous subjective test, must apply in relation to the standard of disclosure relevant in assault and battery, as the Court held that medical evidence was not necessary in this respect. (at p. 565).

It is not stated by the Court, but it may be that the distinction in content of information between the two classes of duty to obtain consent, is based on a distinction between the "old" law, and the "new" law. In the former the determination of what constitutes a sufficient consent to negate the torts of assault and battery, is less onerous than the degree of consent needed for a doctor to escape liability under the latter, modern negligence law, for failure to inform the patient adequately.

For a case apparently to the contrary, in that it indicates that provided the patient submits to the treatment and does not seek information about risks, there is sufficient consent to protect the physician from legal liability, although risks were not disclosed, see *McLean v. Weir, Goff and Royal Inland Hospital* [1977] 5 W.W.R. 609.

104. In fact, in the case itself, the Judge has difficulty in classifying the risk and speaks of the "substantial" "nature and character of the operation", (p. 558)

on the one hand, in contrast to "collateral", (p. 558), "special", (p. 564), "usual", (p. 564), and "material" (p. 559) risks on the other. In *Reibl v. Hughes* (cited *supra*, note 60) Mr. J. Haines expressly adds (at p. 42) to the test expounded in *Kelly v. Hazlett* (at pp. 558-9) for classifying risks, that "it is not only the probability of a particular risk but the severity of its realized consequences which controls its characterization as an 'integral feature of the nature and character of the operation'". (*Kelly v. Hazlett*, *ibid.*).

Thus, according to these cases, what must be disclosed to avoid liability in assault and battery differs from that which needs to be disclosed to fulfill a duty of care in negligence. The latter relates to informing the patient of "*specific* risks within the surgeon's [doctor's] knowledge *peculiar* to the contemplated treatment. The scope of this professional duty of care is defined by the evaluation of a variety of interrelated factors which bear uniquely on each case, factors such as the presence of an emergency requiring immediate treatment; the patient's emotional and intellectual make-up, and his ability to appreciate and cope with the relevant facts; the gravity of the known risks, both in terms of their likelihood and the severity of this realization". (*Reibl v. Hughes*, p. 42, emphasis added).

105. *Kelly v. Hazlett*, *ibid.*, p. 556.

106. *Ibid.*

107. L. Kornprobst, "Les orientations prises, depuis trente ans, par la jurisprudence en matière de responsabilités médicales (II)", La Nouvelle Presse médicale 2(28) 1874 (1973), at p. 1875.

For the situation in Quebec see R. Boucher et al., *supra*, note 62, at p. 472 *et seq.*, where the content of the duty to inform appears to be similar to that in Common Law, but possibly with wider exceptions applicable. Although it is not expressly stated by the authors, it may be implied that the facts which must be included in a disclosure are judged from a patient's viewpoint: "le médecin . . . se devra de donner tous les renseignements nécessaires, toutes les explications suffisantes pour que *le patient* puisse *comprendre la portée* de l'acte auquel il consent" (at p. 474. Emphasis added). I suggest that this means "la portée de l'acte" from the standpoint of the patient and not from that of the doctor, in which case the patient must be told the facts which he considers relevant in assessing consequences, or at least which a "bon père (patient) de famille" would consider relevant, and not only those a doctor would consider relevant.

108. *Cour de Cass.* (civ) 21 Fév 1961 J.C.P. 1961.12129.

109. J. Vidal and J.-P. Carlotti, "Le consentement du malade à l'acte médical", in "Premier congrès international de morale médicale. Rapports" Ordre National des médecins, Paris, 1955, at p. 79.

110. H. et L. Mazeaud et A. Tunc, "Traité Théorique et Pratique de la Responsabilité Civile Délictuelle et Contractuelle", 6e éd. Paris; Éditions Montchrestien, 1965, Tomes I & II, at Tome I, No. 511.

111. For a summary of, and references to, this jurisprudence, see: L. Kornprobst, *op. cit.*, note 12, at pp. 356-7.

112. Note the words "simple", and "intelligible", and, also, perhaps in the same sense of aiding understanding by the patient, "approximative", which are

used by the *Cour de Cassation*, cited *supra*, note 108, when speaking of the requirements of informing for the purpose of obtaining consent.

The requirement of subjective and understanding probably also applies in Quebec law. See, for example, the quote from R. Boucher *et al.*, *supra*, note 107.

113. 26 App. Div. 2d. 693; 272. N.Y.S. 2d. 557 (Sup. Ct. 1966); reversed in part 19 N.Y. 2d. 407; 227 N.E. 2d. 296 (1967).

114. J.R. Waltz and T.W. Scheuneman, *supra*, note 80, at pp. 630-5; in "Katz ed.", *op. cit.*, note 3, p. 605.

115. 42 U.S.L.W. 2063 (Circ. Ct. Wayne County Michigan 1973). Also published in fall in W.H. Gaylin, J.S. Meisler and R.C. Neville eds., "Operating on the Mind (The Psychosurgery Conflict)" New York; Basic Books Inc. 1975 (hereafter referred to as "Gaylin, *et al* eds.") at Appendix, p. 185 *et seq*.

116. Fed. Reg. 13th March 1975, 40 F.R. 50, 11854; 45 C.F.R. § 46.3(c).

117. 21 C.F.R. § 310.102(h), § 312.1.

117a. These DHEW and F.D.A. provisions specifying the scope of the required disclosure of information should be compared with those recently recommended by the Medical Research Council of Canada, ("Ethics in Human Experimentation", *supra*, note 69(a), at pp. 21, 22) which state that the information "should explain the following:

— the procedures that involve the subject, including the use of drugs or radioisotopes.
— foreseeable risks, side effects and discomforts.
— the nature of the experiment, including randomization procedures and the uncertainties of the experiment.
— possible benefits, both to the subject himself and to others, stressing that these benefits are by no means assured.
— the right to withdraw from the experiment at any time without penalty.
— precautions that will be taken to ensure the anonymity of the subject."

118. There has been some discussion whether or not there is a duty to disclose alternative *experimental* treatments which are available. See: C. Fried, *op. cit.*, note 9, Introduction, at p. 29; *Fortner v. Koch*, 272 Mich. 273; 261 N.W. 762 (1935).

One may also consider no treatment as an alternative form of treatment of which the patient must be advised. In this respect it is interesting that R. Boucher *et al* (*supra* note 62, at p. 485) state that there is an obligation to advise a patient of the consequences of refusing treatment. The authors do not suggest it, but this duty could be extended to disclosing the risks and benefits of "no treatment", when this is the result of the doctor's decision rather than the patient's as in refusal of treatment.

119. 21 C.F.R. § 310.102(h).

120. *Ibid*.

121. For example see: W.R. Barclay, "Statement of the American Medical Association. Re: Human Experimentation" before the Subcommittee on Health, Committee on Labour and Public Welfare, United States Senate,

March 8, 1973 (copy supplied to the author by the American Medical Association), at p. 2; N. Hershey and R.D. Miller, *op cit.*, note 63, at p. 33, who interpret the D.H.E.W. definition as only *requiring* the purposes of the procedures to be followed to be disclosed, but who recommend that information on the "general purpose" of the study also be given to the subject on a voluntary basis.

The situation discussed by L.A. Ebersold, "The University of Cincinatti Whole Body Radiation Study for Whose Benefit?", (1973-74) 15 Atomic Energy Law Journal 155, where persons were subjected to experiments with whole body radiation, possibly for defence purposes, without this purpose being disclosed, is instructive when considering whether a disclosure of general purpose should be mandated and suggests that it should be.

B. Dickens, *supra*, note 62, at p. 395, says the question is whether the subject must approve the entire purpose and scheme of the research, or it is sufficient that he consents to what is involved in his own participation. Dickens makes a distinction between giving the subject misinformation, which is unacceptable, and confining information to that pertinent to the subject's participation, which he says may be allowed.

122. If medical research is not limited to medical purposes this will affect the ethical justification for conducting the research, which depends on the validity of the purpose sought in comparison with risks taken; also it may be relevant to know the general purpose in designing adequate protections for subjects, or even in alerting subjects to protect themselves. See the discussion by the "U.S. National Commission" of research involving human subjects carried out by the "Intelligence Community", for example the United States Central Intelligence Agency (C.I.A.) [National Commission for the Protection of Human Subjects, "Summary of Minutes of Meeting July 8-9, 1977", certified by K.J. Ryan 13th Aug. 1977 at p. 2, ditto Aug 12-13, 1977, at p. 1], in which it is stated that special protections, such as "second review" and appointment of a "resident expert" who is identified to subjects as a contact in case of injury, should be instituted for all such research, as the identity of the sponsor or the purpose of the research may not be disclosed for security reasons.

123. Report of a WHO Scientific Group, Wld. Hlth. Org., Technical Report Series, 1968, No. 403, at p. 19.

Such disclosure would be limited to remuneration received above the researcher's normal salary, which would be payable whether or not he conducted the experiment.

124. Which is not to say he would be given the treatment at a future time, as other factors, extrinsic to the doctor's willingness to give the treatment, may indicate that this is undesirable.

125. N. Hershey and R.D. Miller, *op. cit.* note 63, at pp. 62-3.

126. J.A. Robertson, *supra*, note 97 at p. 30.

If there is no express term in the contract of experimentation then whether there is a legal right to compensation will depend on whether a term to this effect can be implied, either from the circumstances or by custom or usage.

127. Also with respect to the language used one must be careful that there is not subtle intentional, or unintentional, deception. For example B. Gray, "Human Subjects in Medical Experimentation", New York; John Wiley & Sons, 1975, at pp. 221-2, found that the consent form used in the experimental study he was investigating, did not use the word research and that the medical and para-medical staff employed euphemisms such as "new drug", rather than experimental drug, when speaking to patient/subjects. (at p. 217).

128. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 39.

129. D.C. Martin, J.D. Arnold, T.F. Zimmerman, R.H. Richart, "Human Subjects in Clinical Research — A Report of Three Studies", N.E.J.M. 279 (26) 1426 (1968), at p. 1427.

130. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 33 and p. 63, recommend that the information should be given in the form of an invitation to participate to avoid coercion.

131. L.C. Epstein and L. Lasagna, "Obtaining Informed Consent: Form or Substance", Arch. Int. Med. 123(6) 682 (1969), found the degree of comprehension of information by research subjects was inversely proportional to the length of the consent form used, all of which contained the basic, essential information necessary to "informed" consent; F.J. Ingelfinger, "Informed (but uneducated) Consent", N.E.J.M. 287(9) 465 (1972), at p. 466.

132. B. Gray, *op. cit.*, note 127, at p. 220.

133. *Ibid.*, at p. 220.

134. *Ibid.*, p. 138

135. B. Barber, J. Lally, J.L. Makarashka and D. Sullivan, "Research on Human Subjects (Problems of Social Control in Medical Experimentation)", New York; Russel Sage Foundation, 1973, at p. 113.

    Also see H.O. Tiefel, "The Cost of Fetal Research: Ethical Considerations", NEJM 294(2) 85 (1976) at p. 86, who concludes that it is necessary for the experimenter to identify with the subject to see him as human and therefore to treat him as such. One of the purposes of obtaining consent is to cause this identification by the researcher to occur, as well as to allow the subject to identify with or reject, at his option, the research endeavour. Thus if the researcher does not himself obtain the consent, part of the protective mechanism of the consent process is lost, although one must look to the *net balance* of protectiveness provided by the consent process and discount for possible coercion involved in the experimenter obtaining consent. The point I wish to make here is that consent can serve as a double identification process: of the subject with the experiment and of the researcher with the subject.

136. It is not internally inconsistent to formulate a non-delegable duty, which may be carried out vicariously, as in such cases it is the liability arising from breach which is non-delegable, not the actual performance, although this may also be made non-delegable in some cases by operation of law or contractual agreement.

In terms of this analysis the non-delegable duties proposed here are the one to obtain "informed" consent, which is non-delegable only as to liability, and the one to ensure that "informed" consent is obtained, which is non-delegable with respect to both liability and performance.

137. R. Slovenko, "Commentary: On Psychosurgery", The Hastings Center Report, 5(5) 19 (1975), at p. 21.

138. See R. Boucher *et al*, *supra*, note 62, at p. 475, citing *Pincovsky v. Tessier* (1930) 36 R.L. 327; B. Dickens, *supra*, note 62, at p. 402. This author also adds that as well as a continuing duty to disclose new factors which become apparent in relation to risk, because the subject consents to a procedure for a particular *purpose*, if the purpose changes he must be informed of this to maintain the validity of his consent (at pp. 403-4).

C. Fried, *op. cit.*, note 9, at pp. 24, 34-35; N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 150.

138a. See, for example, Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at p. 25.

139. See *Johnston v. Wellesley Hospital*, cited *supra*, note 62, for a discussion of the Common Law approach to causation in non-disclosure of information cases.

140. D. Giesen, "La Résponsabilité par Rapport aux Nouveaux Traitements et aux Expérimentations", in "La Responsabilité civile des médecins", *op. cit.*, note 72, p. 63, at p. 69 (footnotes omitted).

141. This is the same line of argument as used by the French jurisprudence with respect to its "loss of a chance of cure" doctrine. This may be described as a duty of a doctor not to lose for a patient, a chance, that he otherwise has, of cure or survival. See P. Lombard *et al op. cit.*, note 78, at p. 14 *et seq*.

The necessary causal link between a doctor's non-disclosure and a patient's injury, in order to establish liability of the former, has been described in some American cases on the basis that the jury (the trier of fact) must determine what a prudent person in the patient's position would have decided if adequately informed, and there is then only causality if the decision would have been different from what it in fact was.

Cobbs v. Grant, cited *supra*, note 62; *Canterbury v. Spence*, cited *supra*, note 62; *Fogel v. Genesee Hospital*, 344 N.Y.S. 2d. 552 (1973); *Cooper v. Roberts*, 286 A. 2d. 647 (1971).

That is, an objective assessment is made of whether the patient would have refused to participate if the full disclosure had been made. In other words the non-disclosure must have caused the decision to participate, where proper disclosure would have reversed this decision from an objective standpoint. This *decision to participate* is then seen as the damage and not the risk which eventuated, which rather quantifies the damage.

This same approach to causation in "non-disclosure cases" is taken by the English Courts. See, for example, *Bolam v. Friern Hospital Management Committee* [1957] 1 W.L.R. 582; [1957] 2 All E.R. 118.

The "loss of a chance" approach looks at the situation from the other side, that is the damage is the loss of a *chance not to participate*, which is present whichever way the patient would have decided with full information. This in fact, imposes strict or risk liability for the non-disclosure, which I suggest is desirable at least when there are no therapeutic reasons for carrying out the procedure, or it is experimental, and possibly even in the purely therapeutic situation, as the doctor may always rely on the justification of "therapeutic privilege" if this is appropriate.

142. P. Lombard *et al*, *op. cit.*, note 78, at p. 165.

Note that although I have suggested that a "loss of a chance" approach should be taken with respect to non-disclosure by physicians, French doctrinal writers have not yet done this. Rather the evolution of this doctrine has been in the area of "la faute médicale", in the more traditional sense of malpractice relating to performance of a medical procedure, such as giving sub-standard treatment, which is then characterized as causing a loss of a chance to receive proper treatment.

143. *Cf.* L. Kornprobst and S. Delphin, *op. cit.*, note 62, at No. 231, who state that the absence of consent transfers the risk of the treatment to the doctor, but the fault of non-disclosure is only actionable if the treatment fails, that is if there is damage. This would make the overall result in a case involving such circumstances the same in the United States and France, the difference being that the claim arises at different times. In the United States there would probably only be nominal damages awarded in assault and battery, for failing to obtain consent, where the treatment was successful. In such a case no claim arises under French Law. But in either case, if the treatment fails, damages appear to be recoverable, providing the appropriate tests of causation are met — see discussion, *supra*, note 141.

G. Boyer Chammard and P. Monzein, *op. cit.*, note 56, at p. 139, state that a doctor is not liable if he acts without consent, if this turns out to be for the good of the patient; R. Boucher *et al*, *supra*, note 62, at p. 478, discuss the situation in Quebec. They say for the doctor to act without consent is fault, but this fault must be the cause of the damage for liability to ensue and it seems submitting a person to a risk he did not agree to take does not itself constitute damage. There is some authority in Quebec, *Beausoleil v. Communauté des Soeurs de la Charité de la Providence* [1965] B.R. 37 per Casey J. and Owen J., that even if there is no fault on the doctor's part, (sic) if he overrules the patient's wishes he carries the risk of having to compensate the patient if bad results occur. This case can be limited however, on its facts, as only applying where a doctor acts *against* a patient's express wishes, rather than without his consent. In a not very clear statement, the majority of the Court in this case, Lefebvre J., Lamontagne J. and Brossard J., seem to hold that because a doctor is only under an obligation of "means" he does not take liability for all resulting risks when he acts without the patient's consent. I suggest that the relevant obligation of means to be applied here relates to the duty to inform, and although the same standard of obligation may also apply to the treatment given this is not pertinent at this stage, and that if there is not the required *diligence in informing*, the damage arising from this fault may be quantified by assessing medical complications caused by the intervention, even those which arise without fault of the doctor.

144. P. Lombard *et al*, *op. cit.*, note 78, at pp. 167-8.

It may be that this approach of the Common Law can be explained by postulating that it applies a similar doctrine to "loss of a chance" at the level of informing. That is the patient must have all chances of choice at this stage, which is consistent with an over-riding autonomy of self-determination principle. In comparison the Civil Law allows for more choice of treatment by the doctor, rather than the patient (which is certainly historically correct), but is more inclined to find liability at a later stage when it determines that the patient lost, not a chance of choice as in Common Law, but a chance of cure, which is more consonant with fully upholding an inviolability principle aimed at protecting the health and well-being of the individual rather than his autonomy. (See *supra*, pp. 4-7.)

145. R. Miller and H.S. Willner, "The Two-Part Consent Form", NEJM 290(17) 964 (1974), at p. 965.

    Also see Fed. Reg. 14 Jan. 1977, 3089, where it is reported that the Clinical Research Center for Vaccine Development (United States) requires volunteer subjects to pass an exam assessing their comprehension of information regarding the research, prior to their being experimentally innoculated.

146. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 41.

147. B. Gray, *op. cit.*, note 127, at p. 200.

148. Fed. Reg. 23rd Aug. 1974, 39 F.R. 165 30653; 45 C.F.R. § 46.305. Deleted by Fed. Reg. Aug. 9, 1975, 33527, on the recommendation of the United States National Commission, *supra*, note 37, Chapter I.

149. See Statement by the Committee on Ethics of the American Heart Association, "Ethical Considerations of the Left Ventricular Assist Device", JAMA 235(8) 823 (1976).

    Also see Declaration of Helsinki, *supra*, note 69, at I Basic Principles, parag. 10, which suggests that an independent physician may obtain consent.

150. On this latter point see J. Viret, "L'expérimentation clinique. Quelques réflexions sur l'aspect juridique du problème," Revue Médicale de la Suisse Romande 89(9) 911 (1969), at p. 915, who says the information must be simplified and put in commonly used and understood language and therefore a doctor should only use "une caricature de la vérité".

151. For example in *Lotspeich v. Chance Vought Aircraft Corporation* 369 S.W. 2d 705 (Tex. 1963), a pre-employment physical examination, including a chest X-ray, indicated tuberculosis which the plaintiff did not become aware of until three years later. The court held that because there was no physican-patient relationship there was no duty to disclose the diagnosis to the plaintiff, there being only a duty in this respect to her employer, who had commissioned the examination.

    See also, *Candler v. Crane Christmas and Co.* [1951] 2 K.B. 164, per Denning L.J., at p. 183.

152. M. Hemphill, "Pre-testing for Huntington's Disease. An Overview", The Hastings Center Report 3(3) 12 (1973); F.R. Freemon, "Pre-testing for Huntington's Disease, Another View", The Hastings Center Report 3(4) 13 (1973).

These authors were specifically speaking of the dilemma of pre-testing for Huntington's chorea, an incurable inherited disease, which may be detected at a relatively young age and which is characterized by the gradual onset of insanity and loss of physical coordination, with death in middle age.

Also see; Article 34 *Code de Déontologie* (France) cited *supra*, note 72, with which the approach I have suggested concurs.

Article 14 *Code of Medical Ethics of the Professional Corporation of Physicians of Quebec*, cited *supra*, note 72.

O. Enjolas, "Morale traditionnelle et progrès en génétique", La Nouvelle Presse médicale 2(13) 865 (1973).

153. See, for example, B.L. Kaiser "Patients' Rights of Access to their Own Medical Records: The Need for New Law", (1975) 24 Buffalo Law Rev. 2:317.

Note that under *The Public Hospitals Act* (Ontario), R.S.O. 1970 c. 378, section 11, "the medical record compiled in a hospital for a patient or an out-patient is the *property of the hospital* . . . " (emphasis added).

154. *Code de la Santé publique* (France), Article R5120.

155. U.S.C. § 552.

156. *Washington Research Project Inc. v. D.H.E.W.* 504 F. 2d 238, *cert. denied* 421 U.S. 963 (1975).

157. Also see Report and Recommendations of the United States National Commission on "Disclosure of Information under the Freedom of Information Act", D.H.E.W. Publication No. (05) 77-0003, at pp. 7-12, 22-4.

157a. Cited supra, note 155.

158. S.Q. 1971 c. 48, as amended by S.Q. 1973 c. 38; S.Q. 1974 c. 42; Statutes of 1975, Bill 36 and Bill 86, Statutes of 1977, Bill 10.

159. *Ibid.*, section 7.

160. J.M. Gustafson, "Ain't Nobody Gonna Cut on My Head!", The Hastings Center Report 5(1) 49 (1975), at pp. 49-50.

161. H.K. Beecher, "Consent in Clinical Experimentation — Myth and Reality", J.A.M.A. 195(1) 124 (1966).

162. E.B. Brody, "The Right to Know. On the Freedom of Medical Information", Journal of Nervous and Mental Diseases 161(2) 73 (1975), at p. 76.

163. *Cf.*, A.M. Capron, *supra*, note 62, at p. 321, who says the aim of the law in requiring consent is to protect the "well-being" of the person. The term "well-being" may be intended to be synonymous with self-protection, or could include a right to self-determination even where this was "non-self-protectively" exercised.

164. H. Jonas, *supra*, note 42, at p. 19.

165. P.A. Crépeau, "Le Consentement du Mineur en Matière de Soins et Traitements Médicaux ou Chirurgicaux selon le Droit Civil Canadien", (1974) 52 Rev. du Barr. du Can. 247, at p. 256; *Cf.*, H.K. Beecher, *supra*,

note 161, who sees the major value of consent as being in the fact that the patient then knows what he is involved in, for instance, an experiment, "and knowing can reject the opportunity if he chooses to do so" (at p. 124). This is an approach that arises from a starting point that consent is a "myth" and therefore the positive willing foreseen by Crépeau and Jonas is an impossibility and the benefit of consent is not in allowing one to participate voluntarily, but in allowing one to *refuse* to do so. The net result of this approach is that one therefore has "consent" when one has the façade of consent and there has been no refusal of consent after a proper effort to obtain it.

166. See W.H.V. Rogers, "Winfield and Jolowicz on Tort", 10th ed., London; Sweet and Maxwell, 1975, (hereafter referred as to "Winfield and Jolowicz") at p. 614.

167. *Ibid.*

168. See *Christopherson v. Bare* (1848) 11 Q.B. 473, at p. 477 where it was decided that lack of consent should be raised under the general issue, not being a matter for "justification" to be pleaded by way of "confession and avoidance". Referred to by J.C. Fleming, *op. cit.*, note 23, at p. 77, f.n. 24.

168a. That the defendant's admitting the act is not a "confession and avoidance" mechanism, as the act itself does not constitute wrong-doing to which the defendant can confess when consent is present.

169. Thus the defendant is limited, in a defence based on consent, by the plaintiff's ability to consent to the act in question — it may be that this is restricted by public policy or public order and good morals.

170. J. Paquin, "Morale et Médecine", Montréal; Immaculée Conception, 1955, at p. 354.

171. G.J. Annas and L.H. Glantz, "Psychosurgery: The Laws Response", (1974) 54 Boston University Law Review, at p. 254.

172. An exception perhaps to the necessity of transfer of power from the patient to the doctor, or where the doctor may be regarded as having the power to "interfere" with the patient vested in him, is the emergency situation, especially where, as in some jursidictions, the doctor may intervene against the patient's will.

173. T.A. Shannon, "The Problem of Interests and Loyalties: Ethical Dilemmas in Obtaining Informed Consent", Bioethics Digest 1:1 (1976).

174. *Ibid.*, pp. 4-5.

175. *Ibid.*, p. 5.

176. *Ibid.*

177. *Ibid.*, p. 7.

178. *Ibid.*, p. 2.

179. See, for example J. Katz, *supra*, note 59, at p. 306.

180. C.H. Baron, M. Botsford and C.F. Cole, "Live Organ and Tissue Transplants from Minor Donors in Massachusetts", (1975) 55 Boston Univ. Law Rev. 2:159, at p. 168.

181. A.M. Capron, *supra*, note 80, at p. 349.

182. See W.E. May, "Proxy Consent to Human Experimentation", Linacre Quarterly 43(2) 73 (1976).

183. Note that "against their will" is not necessarily the same as "without consent". One may act without consent, but not against a person's will, as the act would have accorded with the person's will *if* he could have expressed it. Or one may even act without consent, because the person lacks legal capacity to consent, but not against his expressed will, because he has factual capacity and used this to make his wishes known. In the former case the legality of the act hinges on excéptions to, or implications of, consent, not will; in the latter case, perhaps, a "lacunae" should mean that one must be presumed to be acting against a person's will. That is when a person is factually capable of choosing the failure to give an opportunity of choice causes a presumption to arise that one acted against that person's will, from the mere fact of not consulting his will. It is a separate and secondary question whether or not this is justified in some circumstances.

184. I. Berlin, "Four Essays on Liberty", London; Oxford University Press, 1969, at p. 138.

185. P. Freund, *supra*, note 6, at p. xvi and p. 114.

See also H.K. Beecher, *supra*, note 161, who speaks of the "*myth*" of informed consent a word with a strong connotation of symbolism.

186. P. Freund, *ibid.*, at p. xvii.

187. Cited *supra*, note 115.

188. Discussed by V.C. Heldman, "Behavior Modification and Other Legal Imbroglios of Human Experimentation", (1974) 52 Journal of Urban Law 155, at p. 164 *et seq*.

189. G. Calabresi, "Reflections on Medical Experimentation in Humans", in Freund ed., *op. cit.*, note 6, p. 178, at p. 195.

190. See G. Calabresi, "The Cost of Accidents — A Legal and Economic Analysis", New Haven; Yale University Press, 1970.

191. J.F. Childress, "Compensating Injured Research Subjects: I. The Moral Argument", The Hastings Center Report 6(6) 21 (1976).

192. See also H. Jonas, *supra*, note 42, at pp. 14-15 and p. 17, who speaks of consent being the "non-negotiable minimum requirement" for tapping reserves of self-sacrifice.

193. A.M. Capron, "Legal Considerations Affecting Clinical Pharmacologic Studies in Children", Clinical Research 21(2) 141 (1973), at p. 146.

It is interesting that Capron uses the word "suffer" in describing the purpose of "informed" consent, as "to assure that one *suffers* only those risks he has chosen". (Emphasis added.) This again connotes an element of sacrificiality even though this is positively, rather than negatively, expressed, that is with more emphasis on the right of choice present than the sacrifice involved.

194. For example, see R. McCormick, "Experimentation in Children: Sharing in Sociality", The Hastings Center Report 6(6) 41 (1976) at p. 46.

195. For example, A.M. Capron, *supra*, note 8, at p. 349; F. Rosner, "Modern Medicine, Religion and Law", New York State J. Med. 75(5) 758 (1975), at p. 759.

196. W.E. May, *supra*, note 182, at p. 79-80.

See also I. Berlin, *op. cit.*, note 184, at p. 156, who describes the process of personal identification in this way: "[M]y individual self is not something which I can detach from my relationship with others, or from those attributes of myself which consist in their attitude towards me".

197. J. Fletcher, *supra*, note 62, at p. 644.

198. *Ibid.*, p. 633.

199. See H.O. Tiefel, *supra*, note 135; B. Barber *et al*, *op. cit.*, note 135, at p. 113.

200. H. Jonas, *supra*, note r2, p. 19.

201. P. Ramsay, "The Ethics of a Cottage Industry in an Age of Community and Research Medicine", NEJM 284(13) 700 (1971) at p. 705.

202. P. Ramsay, "The Patient as a Person — Explorations in Medical Ethics", New Haven; Yale University Press, 1970, at p. 5.

203. T. Parsons, "Research with Human Subjects and the 'Professional Complex'", in "Freund ed.", *op. cit.*, note 6, p. 116, at pp. 132-5.

204. B. Gray, *op. cit.*, note 127, at p. 239.

205. See S. Siegel, "A bias for life", The Hastings Center Report 5(3) 23 (1975), at p. 25.

206. G. Edsall, *supra*, note 94, at p. 282.

207. R. Slovenko, *supra*, note 349, at p. 21.

208. A. Meisel, *supra*, note 325, at pp. 107-113, 123-132.

209. See *Kaimowitz v. Department of Mental Health for the State of Michigan,* cited *supra*, note 115, at pp. 194-200, 204 where the Court refused to permit psychosurgery on a mental incompetent on the ground, *inter alia*, that the subject's consent was necessary, but impossible to obtain.

210. For example, see *California Penal Code* (Supp. 1975) § 2670.5(b) "No person . . . who lacks the capacity for informed consent shall be administered or subjected to psychosurgery . . . ".

211. See B. Dickens, *supra*, note 62, at p. 387.

212. Committee on Ethics of the American Heart Association "Ethical Implications of Investigations in Seriously and Critically Ill Patients" Circulation 50(6) 1063 (1974), at p. 1068. In fairness, taking into account the tone of the later statement by the Committee on Ethics of the American Heart Association, *supra*, note 461a, the criticism levelled in my comment probably needs to be modified.

213. W. Wolfensberger, "Ethical Issues in Research with Human Subjects", 155 Science 47 (1967), at pp. 50-51. Also reprinted in "Katz ed.", *op. cit.*, note 3, p. 923, at p. 924.

214. See *infra*, p. 37 *et seq.*

215. See G.J. Annas, L.H. Glantz, B.F. Katz, *op. cit.*, note 171, at p. 49, who quote a social scientist as saying that unrealistic standards for medical research, for example, only breed cynicism.

216. Fed. Reg. 13th March 1975; 40 F.R. 50, 11854; 45 C.F.R. § 46.3(c). Note this definition takes many elements from the Nuremberg Code and the Declaration of Helsinki and, therefore, is of general interest.

217. Fed. Reg. 23rd Aug. 1974, 39 F.R. 165, 30655; 45 C.F.R. § 46.501(b).

218. Fed. Reg. 13th March 1975; 40 F.R. 50, 11854; 45 C.F.R. § 46.2(b) (3). (Emphasis added.)

219. *Ibid.*, 40 F.R. 50, 11856; 45 C.F.R. § 46.9. (Emphasis added.)

220. "A Submission to the Medical Research Council [Canada]: The University of Toronto's Experience with the Review of Research Involving Human Subjects", by T.C. Clark, Director, Feb. 3, 1977, at p. 2. (Made available by kind permission of the authors and the Medical Research Council.)

221. *Ibid.*, pp. 2-3.

222. See *supra*, p. 23.

223. *Cf.* T. Parsons *supra*, note 203, at p. 135, who, speaking of medical experimentation, describes this as taking place in a voluntary association complex and says the most important protection of the individual is his *right to resign* from this complex, which implies not only a positive act being necessary, but, perhaps, some duties attached to the resignation procedure.

Also *cf.* R. Boucher *et al*, *supra*, note 62, at p. 485, who say that in Quebec the patient at all times retains *"son droit de refuser"* as to hold otherwise would be contrary to Article 19 *Civil Code of the Province of Quebec* which statutorily enacts inviolability. Article 20 of this Code expressly legislates a *right of revocation* with respect to organ transplant donors and subjects of experimentation.

224. A.M. Capron, *supra*, note 8, at p. 364.

225. The exception to a contractual relationship being present may be where a doctor was justified in administering treatment against a patient's expressed will, when one could not reasonably imply a contract.

See P.D.H. Skegg, *supra*, note 17; J. Penneau, "Faute et Erreur en matière de responsabilité médicale", Paris; Librairie Générale de droit et de Jurisprudence, R. Pichon et R. Durand-Anzias, 1973, at p. 15, says that in French law it is only when there is no consent present that an action lies in delict, as an action based on a defect in the consent obtained is within the contractual regime of liability.

226. See L. Kornprobst and S. Delphin, *op. cit.*, note 62, at Nos. 16, 113 and 114.

227. See A.G. Guest ed., "Anson's Law of Contract", 24th ed., Oxford; Clarendon Press, 1975, (hereafter referred to as "Anson"), at pp. 5-6.

In comparison, in the Civil Law "consensus ad idem" is judged more subjectively. See J.-L. Baudouin, "Les Obligations", Montréal; Les Presses

de l'Université de Montréal, 1970 at Nos. 71-79. If consent to the contract attracts an objective standard, as in Common Law, this may explain the necessity to evolve the doctrine of "informed" consent to treatment, with its more subjective standard, and also shows one possible reason why the doctrine of "informed" consent developed earlier and more strongly in Common Law.

228. V.C. Heldman, *supra*, note 188, at p. 169, suggests that the use by American Courts of constitutional bases for allowing or preventing medical interventions, shows a move away from narrow contract theories of rights in these situations, to a human rights basis; *Cf.* A Mayrand, *op. cit.*, note 43, at No. 41, who assumes that the same rules, at least as far as capacity is concerned, apply to consent relevant to entering a contract, as to consent needed for the purposes of the rule against inviolability: "Celui qui est incapable de contracter ne pouvant consentir valablement à ce que l'on porte atteinte à sa personne . . . ", which seems to be retaining rights in the medical situation entirely within a contractual framework.

    It must be admitted that establishing a more general foundation for these rights, does not solve the problem of which basic human right of the patient is to predominate, when there is a conflict between one or more of them. I have suggested that any resolution of such a conflict involves a value judgment and that the values of the patient must predominate, with the possible exception that these rights cannot be abused, that is used to achieve a purpose for which they were not intended, such as relying on inviolability of the body to prevent life-saving treatment.

229. W. Prosser, *op. cit.*, note 16, at p. 103.

230. See "Anson", *op. cit.*, note 227, at pp. 8-18, for a brief history of the development of contract in Common Law.

231. J.F. Toole, "Informed Consent", Circulation 48(1) 1 (1973).

232. Here I am only considering whether it is *possible* to obtain "informed" consent. It is another matter to consider the *feasibility* of securing person-to-person "informed" consent in large scale genetic screening programs for example. (See J. Fletcher, R. Roblin and T. Powledge, "Informed Consent in Genetic Screening Programs", Birth Defects 10(6) 137 (1974), at p. 138. The distinction is between possibilities and feasibilities.

233. H.K. Beecher, *supra*, note 161.

234. H.K. Beecher, "Some Fallacies and Errors in the Application of the Principle of Consent in Human Experimentation", Clinical Pharmacology and Therapeutics 3(2) 141 (1962). Reprinted in "Ladimer & Newman eds.", *op. cit.*, note 10, p. 133, at p. 137.

235. L. Portes, "A la recherche d'une éthique médicale", Paris; Masson, 1954, "Du Consentement du Malade à l'Acte Médical", at p. 83-84.

236. *Ibid.*

    Note: It is interesting historically to conjecture whether Beecher knew of Portes' description of consent as "une notion mythique" published twelve years before Beecher's most quoted quote: the "myth" of informed consent.

237. E.D. Pellegrino, "Humanism in Human Experimentation: Some notes on the investigator's fiduciary role", Tex. Rep. Bil. and Med. 32(1) 311 (1974), at p. 316.

238. F.J. Ingelfinger, *supra*, note 131.

239. F.J. Ingelfinger, *ibid.*, thus interprets the requirement of "informed" as being fulfilled with some, or perhaps even total, lack of comprehension of the information given. See *supra*, pp. 15-16, for a discussion of comprehension. Legal capacity only requires the potential to comprehend, not actual comprehension, and thus one could have a legally capable, totally non-comprehending patient or subject.

240. M.J. Vidal and J.P. Carlotti, *supra*, note 109, at p. 83.

241. Thus referring to the "dual consent" concept discussed earlier (*supra* p. 36), Vidal and Carlotti require only free and clear consent to the medical contract and not necessarily to the treatment given under it.

242. For examples of such an attitude see: Committee on Ethics of the American Heart Association, *supra*, note 212; J.F. Toole, *supra*, note 231.

243. See *supra*, pp. 3-10.

244. R. McCormick, "Proxy Consent in the Experimentation Situation", Perspectives in Biology and Medicine 18(1) 2 (1974), at p. 3.

245. See C. Freid, *op. cit.*, note 9, at p. 21.; *Cf.* P.D.G. Skegg, *supra*, note 17, at pp. 513-4, who argues that such implications of consent are artificial and that justification of emergency interventions should rather be based on a "doctrine of necessity".

Also see J.G. Fleming, who, in the earlier edition of his text, *op. cit.*, note 21, at p. 78, regarded the justification of the emergency intervention as being based not on implied consent, but on "the preservation of life", which was changed in the later edition, *op. cit.*, note 23, p. 81, to "the humanitarian duty of the medical profession".

Cf. X. Ryckmans and R. Meert-van de Put, *op. cit.*, note 62, at No. 569, who say consent is not necessary when the treatment involves no danger. This is to make a distinction between consent to treatment and consent to risks, and to assume that consent is only necessary in relation to the latter.

Also see P.J. Doll, *supra*, note 36, at No. 41, who argues that in the emergency situation one has present a notion of "tentative autorisée", which is sufficient justification for the intervention, although, apparently, it does not amount to an implying of the "free and clear" consent which is normally required.

246. See: L. René, "Risque et responsabilité en chirurgie", in "Le médecin face aux risques et à la responsabilité", textes recueillis par M. Eck, Paris; 1968 (hereafter referred to as "Eck, ed."), at pp. 242-3, who says consent is not required, if it is not feasible or humane to obtain it; X. Ryckmans and R. Meert-van de Put, *ibid.*, at Nos. 570 and 572 who allow "therapeutic privilege" and urgency of the situation as a justification for acting without consent; R. Boucher *et al*, *supra*, note 62, at pp. 477, 479 *et seq.*, who analyze the *Beausoleil Case* (cited *supra*, note 143) and show that in Quebec

it is not clear if one can legally override a patient's wishes. They conclude (at p. 485) that a doctor probably cannot force a competent adult patient to receive care he refuses; *Cf.* A. Mayrand, *op. cit.*, note 43, No. 38, who argues this is justified to save life, but admits the situation is not clear in Quebec; L. Kornprobst, "Peut-on admettre un refus de transfusion sanguine par convictions religieuses?", La Nouvelle Presse Médicale 3(19) 1262 (1974), who says there is no damage in saving the patient against his will and hence such an act would not be legally actionable; R. Piédelièvre et E. Fournier, "Médecine légale", Paris; Batlière, 1963; Tomes I and II, at Tome I, p. 103, say the strict juridical review is that a patient can refuse treatment.

247. D.A. Frenkel, "Consent of Incompetents (i.e. Minors and the Mentally Ill) to Medical Treatment", Unpublished paper presented at the Third World Congress on Medical Law, Ghent, Belgium, Aug. 19-23, 1973, p. 3, cites two United States cases *Erikson v. Dilgard* 252 N.Y.S. 2d. 705, and *In re Brook's Estate* 32 Ill. 2d. 361; 205 N.E. 2d. 435 (1965), which upheld the patient's right to refuse life-saving treatment, and which show, as a corollary, that consent is always necessary where the patient can give it. However, he says these cases are contrary to the general rule that a patient may not refuse life-saving treatment.

J.R. Mason, *supra*, note 93, at p. 327, f.n. 146, argues that as Judges can order non-consensual emergency treatment this shows that consent is not always necessary.

Application of President Directors of Georgetown College 331 F. 2d. 1000 (D.C. Cir.), certiorari denied 377 U.S. 978 (1964), where the Court ordered a transfusion to be carried out on a competent adult woman despite her express denial of consent.

Cf., *In re Brook's estate*, one of the cases relied on by Frenkel above, where the court held a circuit court's order to administer a blood transfusion against the will of the competent adult patient was unconstitutional as against freedom of religious belief.

See also *Schloendorff v. Society of New York Hospital*, cited *supra*, note 15.

248. For examples of statements that consent is necessary in *all medical research* see: Declaration of Helsinki, *supra*, note 69, at I. Basic Principles, parag. 9; D.J. Whalan, "The Ethics and Morality of Clinical Trials in Man", Medical Journal of Australia 1(16) 491 (1975), at p. 493; I. Ladimer, "Ethical and Legal Aspects of Research on Human Beings", in "Ladimer and Newman eds.", *op. cit.*, note 10, p. 179, at p. 503. This is an extract from the unabridged article I. Ladimer, "Ethical and Legal Aspects of Medical Research on Human Beings", (1954) 3 Journal of Public Law 467; G. Calabresi, *supra*, note 189, at p. 195; Canada Council, Report of the Consultative Group on Ethics, "With Respect to Research Involving the Use of Human Subjects", May 1976; *Cf.* A. Decocq, *op. cit.*, note 4, at No. 334, who tentatively proposes that it may be a fault on the patient's part to refuse therapeutically needed experimental treatment, if it is known to be harmless. This may mean consent is not needed in such a situation, which, if it exists at all, would be very rare according to this jurist.

249. The most universally accepted statement of this requirement is the Declaration of Helsinki *ibid*.

Also see Medical Research Council Report (United Kingdom), *supra*, note 66, which states that consent is essential in non-therapeutic research; Royal College of Physicians Committee (United Kingdom), *supra*, note 67, at p. 2; J.F. Childress, *supra*, note 191, at p. 25.

250. C. Blomquist, "Ethical Guidelines for Biomedical Research", Annals Clinical Research 7(6) 291 (1975), at p. 293.

251. Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at p. 25. But note the provision in this Code goes beyond the use of information already obtained about a person, to allowing use of the remainder of "partly used . . . samples obtained for diagnostic or treatment purposes, tissues obtained during surgical treatment, or information stored in registers or data banks . . . for research purposes".

Statement by the Medical Research Council (United Kingdom), "Responsibility in the Use of Medical Information for Research" B.M.J. 1973.(1).213. The use of such information is subject to complying with certain safeguards, but these do not include a right of refusal of the patient to have his records used.

J.A. Baldwin, J. Left and J.K. Wing, "Confidentiality of Psychiatric Data in Medical Information Systems", British J. Psychiatry 128:477 (1976), at p. 423.

252. M.B. Visscher, "Ethical Constraints and Imperatives in Medical Research", Illinois; Charles C. Thomas, 1975, at p. 25.

253. Under the D.H.E.W. Regulations, 45 C.F.R. § 46.3, such epidemiological or retrospective research would be regarded as research on human persons requiring "informed" consent.

See also N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 17, who state that research "need not be [an] interactive [process]; observation of humans through a one-way glass, by tape recording their conversations, or by examining their records may be classified as research . . . ".

254. For example B. Dickens, *supra*, note 62, at p. 397.

255. M.D. Eilenberg, R. Williams and L.J. Witts, "New Horizons in Medical Ethics: Research Investigation in Adults", B.M.J. 2(860) 220 (1973), at p. 223, who state that an ethical review committee at Northwick Park Hospital, Middlesex has a list of "minor procedures", where the doctor does not need to ask consent, as this would be "more upsetting . . . than otherwise" to the patient.

256. Fed. Reg. 13th March 1975, 40 F.R. 50, 11856; 45 C.F.R. § 46.10(c). This is a possible, but probably unjust interpretation of this section, when it is read in the full context of the Regulations.

257. One can distinguish the therapeutic exceptions where consent may not be required at this level, as in those cases the person is not being used for any purpose extrinsic to himself and as one is one's own purpose, therefore pursuing this intrinsic purpose is not a *use* of the person, whether with or without his consent.

258. C. Fried, *op. cit.*, note 9, at p. 23.

258a. For instance, by being a carrier of, but not a sufferer from, some serious infectious disease.

259. See W. Modell, "Let Each New Patient be a Complete Experience", in "Ladimer & Newman eds.", *op. cit.*, note 10, p. 73 at p. 77; F.J. Ingelfinger, "Those 'Ingredients Most Used by Doctors'", NEJM 295(11) 616 (1976); P.L. Bereano, *supra*, note 39, at p. 88, who says that when technology assessment is involved in a court adjusting the interests between parties to litigation, the court must take into account how this will affect the diffuse and numerous interests of *non-parties*; D.S. Greenberg, "Drug Advertising on T.V.: A New Inquiry", NEJM 294(17) 963 (1976).

Also see and compare: S.C. Schoenbaum, B.J. McNeil and J. Kavet, "The Swine-Influenza Decision", N.E.J.M. 295(14) 759 (1976), for an analysis of the "swine-flu" vaccination program which shows "non-subjects", that is non-participants in the vaccination program, may benefit directly from a certain level of participation of subjects, as this will reduce the risk of an epidemic in which "non-subjects" would be more likely to be infected.

260. A.B. Hill, "Medical Ethics and Controlled Trials", B.M.J. 1963.1.1043, at p. 1046.

261. *Supra*, p. 28 *et seq*.

262. X. Ryckmans and R. Meert-van de Put, *op. cit.*, note 62, at No. 595.

263. J.R. Waltz and T.W. Scheuneman, *supra*, note 80, in "Katz ed.", at p. 604.

264. A. Decocq, *op. cit.*, note 4, at No. 369.

265. J.K. Wing, "The Ethics of Clinical Trials", Journal of Medical Ethics 1975:1:174.

266. J. Hamburger, "Protection of Donor Rights in Renal Transplantation", in V. Fatturosso ed., "Biomedical Science and the Dilemma of Human Experimentation", Paris, Council for International Organizations of Medical Sciences, 1967, p. 44. Reprinted in "Katz ed.", *op. cit.*, note 3, p. 621.

267. E. Cahn, "Drug Experiments and the Public Conscience", in Paul Talalay ed., "Drugs in our Society" Baltimore; The John Hopkins Press, 1964, p. 255. Reprinted in part in "Katz ed.", *ibid.*, p. 721.

268. A.M. Capron, *supra*, note 8, at p. 373.

269. Certainly a person cannot consent to likely death or certain serious harm, but what is reasonable is to some degree a value judgment. For instance one can query if the risk taken in the *Halushka Case* (cited *supra*, note 63), that is of general anaesthetic and cardiac catheterization, had been fully disclosed and consent obtained, whether this would have been objectively reasonable or not.

270. T.A. Shannon, *supra*, note 173, at p. 2.

271. See for example: *Marshall v. Curry* [1933] 3 D.L.R. 266; 60 Can. C.C. 136 (N.S. S.C.); *Mulloy v. Hop Sang* [1935] 1 W.W.R. 714 (Sask. C.A.); *Murray v. McMurchy* [1949] 2 D.L.R. 442; I N.W.R. 989 (B.C.); *Cour Cass.* 15 mars 1966 J.C.P. 64.4.67; *Trib. Civ. Seine* 25 janv. 1949, Gaz. Pal. 1949.1.217; H.M. Street, "The Law and Torts", 6th ed. London; Butterworths, 1976, at p. 75, f.n. 4, says there is a striking absence of English

cases litigated on the basis of consent in the medical relationship, and one of the very few is *Beatty v. Illingwoth* (1896) British Medical Journal 21st Nov. 1896, p. 1525; *Mohr v. Williams* 104 N.W. 12 (Minn. 1905); *Kennedy v. Parrot* 90 S.E. 2d. 754 (N.C. 1956); *Dufresne v. X* [1961] C.S. 119 (Qué.); H.P. Green & A.M. Capron, "Issues of Law and Public Policy in Genetic Screening", Birth Defects: Original Article Series, 10(6) 57 (1974), at p. 65; J.G. Fleming, *op. cit.*, note 23, Chapter 1, at p. 81.

272. See: F.H. Beale, "Consent in the Criminal Law", (1895) 8 Harvard Law Review 317. There has been controversy in Common Law jurisdictions whether or not consent to an act which is criminal, bars a civil action to recover the damage inflicted. The opposing views are that allowing the civil action has a deterrent effect and, on the other hand, that one should not be compensated when one has willingly participated in a criminal act; J.G. Fleming, *ibid.*, pp. 80-81, who discusses *Matthew v. Ollerton* (1693) Comb. 218, which held that the plaintiff's consent to an act which was "unlawful" did not bar the plaintiff's civil right of action. Fleming suggests that as prior to 1694 trespass involved a fine payable to the Crown, this may have influenced the Court in this "dictum"; W. Prosser, *op. cit.*, note 16, at p. 107; G. Boyer Chammard et P. Monzein, *op. cit.*, note 56, at p. 70.

    See *infra*, p. 105 *et seq.*, for a discussion of what conduct constitutes a criminal act in the medical context.

273. A. Decocq, *op. cit.*, note 4, at Nos. 377-8.

274. See, "Notes: 'The Sale of Human Body Parts'", (1974) 72 Michigan Law Rev. 1182, at p. 1238.

275. E. Nizsalovszky, *op. cit.*, note 13, at p. 65.

276. J.J. Lynch, "Human Experimentation in Medicine: Moral Aspects", in "Ladimer & Newman eds.", *op. cit.*, note 10, at p. 289.

277. This argument is fully presented by Pope Pius XII in "The Moral Limits of Medical Research and Treatment", 44 Acta Apostolica Sedis 779 (1952) Rome, where he likens the rights one has over one's body to a "usufruct" — a right of use but not of destruction, or one may say not of "waste", in the Common Law Real Property sense of this term.

278. E. Cahn, "The Lawyer as Scientist & Scoundrel: Reflections on Francis Bacon's Quadricentennial", (1961) 36 New York University Law Rev. 1, at p. 12.

278a. Note that the Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at p. 22, does not require written consent, but recommends it.

279. P. Lombard *et al*, *op. cit.*, note 78, at p. 116.

280. Fed. Reg. 13th March 1975, 40 F.R. 50, 11854; 45 C.F.R. § 46.10.

281. *Loi sur Les Services de Santé et Les Services Sociaux* L.Q. 1971, c. 48, Art. 3.2.1.11.

    See also O. Reg. 100/74, 49 pursuant to *The Public Hospitals Act* (Ontario) R.S.O. 1970, c.378, section 39.

282. P.A. Crépeau, *supra*, note 165, at p. 258.

283. See, for example, Article 21 *Civil Code of the Province of Quebec*.

Pro Forma Act: *Human Tissue Gift Act* (1965) (Proceedings of Conference of Commissioners on Uniformity of Legislation in Canada (1965) 104) on which all the Common Law Provinces in Canada have based their "organ donation" Acts.

Pro Forma Act: *American Anatomical Gift Act* 1968 (8 Uniform Law Annotated, Master Edition (1972) 22) on which the states of the United States have based their Acts.

Human Tissue Act (1961) 9 & 10 Eliz. 11 c.54 (England).

Tissue Grafting & Processing Act (1955-1966) N.S.W. (Australia).

See also The Law Reform Commission (Australia), Working Paper No. 5, 28 Jan. 1977 "Human Tissue Transplants". And by the same body "Human Tissue Transplants" Report No. 7, Canberra; Australian Government Publishing Service, 1977, especially Draft Legislation "*Transplantation and Anatomy Ordinance 1977*", Part III, Donations of Tissue after Death.

For a report on recent French legislation on transplants, see London "Times" 21st Dec. 1976 and *supra*, note 35.

284. Article 20 *Civil Code of the Province of Quebec* at least allows, even if it does not require, written revocation of consent. See P.A. Crépeau, *supra*, note 165, at p. 258, who says that writing is only a matter of form and not of substantive validity of the revocation. The provision states that "[the] consent must be in writing; it may be revoked in the same way". I suggest that the proper interpretation of this is that the verb "may" is to be contrasted with "must", which indicates that the latter part of the provision is not obligatory; and that the reason for including this provision on revocation, is to rebut any implication that as the "consent must be in writing", so must its revocation. That is revocation is not limited to a written form, rather the provision in this respect is purely facultative.

Also see A. Mayrand, *op. cit.*, note 43, at No. 62, who adds that although a written consent under Article 20 may be instantaneously withdrawn orally, "[l]e droit de révocation peut être exercé fautivement et donner lieu à un recours en dommages-intérêts".

285. 45 C.F.R. § 46.103(c) (United States D.H.E.W. Regulations).

286. B. Gray, *op. cit.*, note 127, at p. 204.

287. E. Cahn, *supra*, note 278, at p. 11.

288. For example at Common Law "duress" has a very limited meaning of violence, or threats of violence, to the person of the contracting party, or to his parent, wife, or child. See M.P. Furmston "Cheshire & Fifoot's 'Law of Contract'", 9th ed. London: Butterworths, 1976, (hereafter referred to as "Cheshire and Fifoot") at p. 286.

"Undue influence" is described as an equitable principle wider than duress, which consists of any pressure which prevents a party from exercising an independent judgment. *Ibid.*, pp. 285-94.

Article 991 *Civil Code of the Province of Quebec* provides that: "Error, fraud, violence or fear, and lesion are causes of nullity in contracts . . . ".

Also see Article 1109 *Code Napoléon* (France).

With respect to the standard against which coercion, duress or undue influence should be judged for the purpose of determining the validity of "informed" consent to medical interventions, I suggest that even if this is normally objective, that is the threat must be such as to overcome the will of a reasonable man, one must additionally look to the state of mind induced in the patient, taking full account of his particular susceptibilities to the extent that these increase coercion, to ascertain whether there was coercion to consent to a particular medical intervention.

289. See *supra*, pp. 36-37.

290. "Cheshire & Fifoot", *op. cit.*, note 288, at p. 291.

291. A. Mayrand, *op. cit.*, note 43, at No. 34.

292. G. Boyer Chammard & P. Monzein, *op. cit.*, note 56, at p. 141. See pp. 141-150 for a full discussion of the relevant jurisprudence.

293. *Cour de Cass.* 29 mai 1951, referred to *ibid.*, at p. 141.

294. Note that this reasoning recognizes the distinction between the two consents (see *supra*, pp. 36-37), that is between consent to the contract and the contractual obligation to obtain consent and the Court is speaking of the burden of proof in relation to the latter.

295. For a summary of the Common Law position with respect to defects of consent, discussed in relation to consent to human medical experimentation, see B. Dickens, *supra*, note 62, at p. 395 *et seq.*

Also see A.R. Holder, *op. cit.*, note 54, at p. 276, who says duress vitiates consent and therefore assault and battery actions will lie in such circumstances; and further that duress is a tort in itself and, that if this is committed by any person associated with, or funded by, a federal agency of the United States Government, then one also has, in that jurisdiction, a violation of constitutional rights; W. Prosser, *op. cit.*, note 16, at p. 106, who likewise states that duress invalidates the consent relevant to barring certain tort actions.

296. See *supra*, pp. 29-30 and *infra*, pp. 107-109.

297. B. Gray, *op. cit.*, note 127, at p. 205.

298. See also H.M. Spiro, "Constraint and Consent — On Being a Patient and a Subject", N.E.J.M. 293(22) 1134 (1975), who supports this finding. He says the physician-patient relationship is so strong that consent cannot be considered an act of free will, as the patient tries to please the physician; *Cf.* L.B. Berman, "Ethics of Studies in Anephric Patients", N.E.J.M. 286(15) 842 (1972), who fails to see coercion in the physician-patient relationship, because "informed consent is between people well known to each other and bears no resemblance to the caricature of a remote scientist intimidating a frightened patient".

299. See *infra*, p. 67 *et seq.*

300. F.J. Ingelfinger, *supra*, note 131.

301. See F.J. Ayd, "Motivations and rewards for volunteering to be an experimental subject", Clinical Pharmacology and Therapeutics 13(5)(2) 771 (1972), at p. 777, who gives an example of cancer patients participating in research for such reasons.

302. S.W. Bloom, "The Doctor and His Patient: A Sociological Interpretation", New York; Russell Sage Foundation, 1963, at p. 218 and at p. 231, f.n. 7, referring to W. Caudill, "The Psychiatric Hospital as a Small Society", Cambridge Mass; Harvard Univ. Press, 1958.

303. E. Goffman, "Asylums, essays on the social situation of mental patients and other inmates", Chicago; Aldine, 1961. This and other references to Goffman's writings are given by S.W. Bloom *ibid.*, at f.ns. 10, 11 and 12.

In the area of medical experimentation one should consider as analogous relationships to that between doctor and patient, those between students and teachers, between military personnel, and between laboratory, or hospital, workers and research staff, etc. That is, wherever there is a relationship in which one person is in some position of authority over another, which authority may be transmitted in a request to act as a volunteer subject for experimentation.

304. S.W. Bloom, *ibid.*

305. See R.N. Smith, "Safeguards for Healthy Volunteers in Drug Studies", The Lancet 1975.II.449, who gives details of these practices.

306. This "case" is reported by S.L. Chorover, "Psychosurgery: A Neuropsychological Perspective", (1974) 54 Boston Univ. Law Rev. 231, at p. 241.

307. See C. Fried, *op. cit.*, note 9, at p. 36. Also the "*Willowbrook experiments*", (see "Katz ed.", *op. cit.*, note 3, at pp. 1007-10; G. Edsall, *supra*, note 24, at pp. 283-5; G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at pp. 179-83; and *New York State Association for Retarded Children, Inc. v. Carey* 393 F. Supp. 715 (1975), for a description of these experiments and the Willowbrook institution) could be considered in this light. There agreement of the parents to allow their mentally defective child to participate in a "hepatitis study" was a condition for obtaining a "hard-to-get" place in the institution for the child.

308. M.H. Pappworth, "Human Guinea Pigs Experimentation on Man", London; Routledge and Kegan Paul, 1967, at p. 216.

309. Note that "payment" is not necessarily restricted to money, but can include such compensation as academic credit, better grades, special privileges etc. Where not otherwise impliedly or expressly indicated the comments on payment should be read as applicable in this extended sense.

Also note that payment may be regarded as inducement rather than coercion. It is submitted, however, that undue inducement amounts to, or has the same effect as, coercion, in that both affect the voluntariness of consent. What is undue depends on the circumstances of each case.

310. 28 Eng. Rep. 838, at p. 839 (Ch. 1762).

311. See, for example, S. Shipko, "Human Experimentation: From the Other Side", NEJM 289(17) 924 (1973).

See also Fed. Reg. 14th Jan. 1977, 3076-3091, at Part IV. Reports to the Commission. Chapter 8. Philosophical Perspectives 3086, for a summary of a submission to the United States National Commission by Dr. Wartofsky, in relation to the coercive effects on prisoners of payment for participation in research.

312. C. Fried, *op. cit.*, note 9, Introduction, at p. 166.

313. R. Nerson, *supra*, note 48, at pp. 676-7; R. Savatier, *supra*, note 36; P. Lombard *et al*, *op. cit.*, note 78, at p. 242; J. Caroff, "Problèmes moraux et responsabilité du médecin lors des essais thérapeutiques", Thérapie 1971 xxvi, 1107, at p. 1113; P.-J. Doll, *supra*, note 36.

In fact, under traditional Civil Law doctrine not only contracts of sale, but all contracts of which the human person was the object, were forbidden. This policy underlies Article 1780, *Code Napoléon* and Article 1667 *Civil Code of the Province of Quebec* which only permits a person to hire out his service "for a limited term, or for a determinate undertaking". (Article 1667 *Civil Code of the Province of Quebec*.)

314. P.-J. Doll, "L'aspect moral, religieux et juridique des transplantations d'organes", Gaz. Pal. 1974.2. doctr. 820, 28 Sept. 1974, at p. 821; R. Nerson, *ibid*.

315. It is possible to argue that in Common Law Canada there is case-law support for a view of the law that allows "compensation" or even payment for participation as a subject of medical research, in that the Court in the *Halushka Case* (cited *supra*, note 63) impliedly, by not commenting that the payment made to the volunteer subject in the experiment involved was illegal, supported the validity of it. Certainly payment of experimental volunteers is so public and widespread in both the United States and Canada that it could almost be regarded as formulation of law by "common custom".

Also see Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at p. 24, which allows compensatory remuneration and even "reward" remuneration, provided it is not excessive so as to serve "as an unethical inducement to participate in a research project".

Inter vivos sale of organs or tissue is not prohibited in the United States, or England, nor is "post-mortem" sale in England except that there are legal problems involved due to the fact that, at Common Law, the rule is that there can be no property in a dead body.

See D.W. Louisell, "Transplantation: Existing Legal Constraints" in G.E.W. Wolstenholme and M. O'Connor eds., CIBA Foundation Symposium, "Ethics in Medical Progress: with special reference to transplantation", London; J.A. Churchill Ltd. 1966, (hereafter referred to as "Wolstenholme and O'Connor eds.") p. 78, at p. 87; A.T.H. Smith, "Stealing the Body and its Parts", [1976] Crim. L. Rev. 622.

In the United States the *Uniform Anatomical Gift Act* (cited *supra*, note 283) has an unclear effect with respect to "post-mortem" sale of body parts, (see Notes, The Sale of Human Body Parts", (1974) 72 Michigan Law Rev. 1182,

at p. 1248) and there is some State legislation, in Delaware for example, prohibiting payment.

In Common Law Canada *inter vivos* sale of all tissues and organs except blood is prohibited: see for example *Ontario Human Tissue Gift Act* S.O. 1971 c.83, s.10.

The current legal situation in Australia is the same as in England, but the legislation just proposed by The Law Reform Commission of Australia (cited supra, note 283, at Part VII — Prohibition of Trading in Tissue, section 40) would not only make all sales of tissue void, but imposes a fine of up to $A500 for being involved in such an act. An express exception to this provision allows for "reimbursement of expenses" incurred by the donor.

Note that in the United Kingdom no payment for "foetal material" is allowed beyond meeting the costs incurred ("The Use of Foetuses and Foetal Material for Research", Report of the Advisory Group, London; Her Majesty's Stationery Office, 1972, at p. 9); and in the United States the National Commission, in its report on foetal research, recommended that no monetary or other inducement to terminate pregnancy for the purposes of research be allowed. This was enacted as subordinate legislation in Fed. Reg. 8th Aug. 1975, 33529; 45 C.F.R. § 46.206. Depending on whom one considers to be the experimental subject here, the mother and/or the child, this could be interpreted as a prohibition of payment of an experimental subject in order to eliminate any possibility of coercion.

With respect to payment for participation in medical research it is also, relevant legally to consider whether such participation constituted a sale or a service. See *Perlmutter v. Beth David Hospital* 123 N.E. 2d. 792 (1954).

316. See, for example, B. Dickens in "A Submission to the Medical Research Council: The University of Toronto's Experience with the Review of Research Involving Human Subjects", *supra*, note 220, at p. 41.

317. A. Mayrand, *op. cit.*, note 43, No. 60.

318. *Ibid.*, No. 61.

F. Heleine, "Le dogme de l'intangibilité du corps humain et ses atteintes normalisées dans le droit des obligations du Québec contemporain", (1976) 36 Rev. du Barr. du Qué. (1)2, at pp. 55-63, also expresses doubt as to whether Article 20 forbids payment for experimentation.

319. P.A. Crépeau, *supra*, note 165, at p. 257.

320. See the discussion of "special subjects", especially that relating to prisoners, *infra*, p. 94 *et seq*.

321. E. Cahn, *supra*, note 267.

322. D. Daube, "Transplantation: Acceptability of Procedures and the Required Legal Sanctions", in "Wolstenholme and O'Connor eds.", *op. cit.*, note 315, p. 188, at p. 198.

323. B. Freedman, "A Moral Theory of Informed Consent", The Hastings Center Report 5(4) 32 (1975), at p. 36.

This statement must be read as based on the belief that in any defined community each person has a right to a certain minimum standard of living,

which differs with each community, but that there is also a universal lowest common denominator in this respect, which would give a person a right, for example, against certain conditions of imprisonment.

324. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 65.

325. Fed. Reg. 23 Aug. 1974, 39 F.R. 165, 30655; 45 C.F.R. § 46.404(4).

326. Issued by the Association of the British Pharmaceutical Industry, London, 1970, at p. 2.

327. This same type of "Catch-22" situation is demonstrated with regard to the requirement of written consent which is normally regarded as a safeguard for the patient. See R.W. Smithells, R.W. Beard and a barrister, "New Horizons in Medical Ethics. Research Investigations and the Foetus" B.M.J. 1973.2(864) 464, at p. 465, per R.W. Beard, who comments that written consent may be an unreasonable influence on a patient not to withdraw from an experiment if he later changes his mind.

328. G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 241.

329. See M.H. Pappworth, *op. cit.*, note 308, at p. 82.

Report of the Committee to Investigate on Medical Experiments on Staff Volunteers (United Kingdom), *supra*, note 326, at § 3:2.

330. A ban on psychosurgery could be viewed in this way.

331. See *infra*, pp. 102-103.

332. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 65.

333. Deception is defined for the purpose of human experimentation, by the Canada Council Consultative Group on Ethics (*supra*, note 248, at p. 15) as the intentional misleading of a subject or subjects to believe that the procedures and purposes of a research project are not what they actually are. There is a problem in definition here because of the intentional requirement. Legally one usually sees deception, in a general sense, as encompassing misrepresentation, which may be innocent or negligent, both of which are unintentional, or fraudulent, which requires intention to deceive. It is probably best, in the context of medicine and medical experimentation, to reserve use of the word "deception" to situations where the physician or researcher knew of the misrepresentation or had no belief in the truth of the representation giving rise to the deception, and to deal with unintentional deceptive influences as either innocent or negligent misrepresentation, or within doctrines of coercion or mistake.

334. See, for example, *Bell v. Lever Bros.* [1932] A.C. 161.

It is also worth mentioning that with respect to mistake the remedies are complicated by the fact that the historical division of Common Law and Equity has affected the area, each of these courts having its own rules on the matter. See "Anson", *op. cit.*, note 227, at pp. 315-7.

335. "Anson", *ibid.*, at pp. 287-8.

336. See "Anson", *ibid.*, p. 271. But note that the effect of mistake in Equity may be different from what it is at Common Law. (Anson, *ibid.*, pp. 315-7.)

337. "Anson", *ibid.*, at p. 271 *et seq*.

338. See: Article 992 *Civil Code of the Province of Quebec;* Article 1110 *Code Napoléon*.

339. See: J.-L. Baudouin, *op. cit.*, note 227, at Nos. 99-123.

See also: Office de Révision du Code Civil, Comité du Droit des Obligations, "Rapport sur les obligations", XXX, Montréal, 1975, Articles 29-33 and 52-61 and the doctrine and jurisprudence cited in the commentary attached to these Articles.

340. At Civil Law, if the rule requiring nullity of the medical contract for mistake, was held to be one applied in the public interest, then any interested person, or the Court, *ex proprio motu*, could invoke the declaration of nullity.

See "Rapport sur les obligations", *ibid.*, at Article 54.

Also see Article 1000 *Civil Code of the Province of Quebec* and Article 1117 *Code Napoléon*.

341. See *supra*, pp. 17-21.

342. See, for example, *O'Brien v. Cunard S.S. Co.* (1891) Mass. 272; 28 N.E. 266.

343. See, for example, *Smythe v. Reardon* [1948] Q.S.R. 74; *Papadimotropoulos v. The Queen* (1957) 98 C.L.R. 249; *R. v. Harms* [1944] 2 D.L.R. 61; *R. v. Bolduc and Bird* (1967) 59 W.W.R. 103 (B.C. C.A.).

344. This term is used as defined in note 333, *supra*.

345. E.A. Carr, "Discussion", Clinical Pharmacology and Therapeutics 13(5) 790 (1972), at pp. 791-2.

346. The rate of autopsy in some hospitals is as high as 90 per cent of deaths. See Law Reform Commission (Australia) Working Paper, *supra*, note 283, at p. 74.

347. E.A. Carr, *supra*, note 345.

348. There is here deception of all subjects, but the content of it differs between the terminally and non-terminally ill.

349. See for example: Fed. Reg. 13th March 1975, 40 F.R. 50 11854; 45 C.F.R. § 46.3(c).

350. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 31.

351. L. Lasagna, "Drug Evaluation Problems in Academic and Other Contexts", Annals of the New York Academy of Sciences 169:506 (1970). Reprinted in "Katz ed.", *op. cit.*, note 3, at p. 689; E.D. Pellegrino, *supra*, note 327, at p. 316; R.J. Prineas, "Common Problems in Clinical Trials Medical Journal of Australia 1971.2(8) 425, at p. 430.

352. It is a moot point whether one could have "informed" consent to deception. I suggest the answer is probably not.

353. See: "Notes", Yale Law Journal, *supra*, note 62, at p. 1563, f.n. 91; "Anson", *op. cit.*, mote 227, at pp. 233-242.

As to what conduct amounts to legally operative misrepresentation, normally this requires a positive verbal or non-verbal representation of fact and there is probably no obligation to inform the other party of his mistaken belief when this has not been induced by an act of the party knowing the true circumstances. However, an exception to this general rule is found in confidential or fiduciary relationships, when there is a positive duty to disclose.

Also B. Dickens (*supra*, note 316, at p. 36) says deception includes stating half-truths and that the line between allowable non-information and misinformation is fine. That is one could argue, as in other areas, that even though there may be no initial obligation to disclose, if one commences to do so it must be done fully.

354. See: H. et L. Mazeaud et J. Mazeaud "Leçons de Droit Civil" 5ième éd. Paris; par M. de Juglart; Ed. Montchrestien, 1972, Tomes I and II, at Tome II "L'erreur, nos. 161-186, "Le dol", nos. 187-198 and "Les effets de la responsabilité civile", at No. 602 *et seq*.

Code Napoléon Articles 1382-3 (delict); 1142, 1144 (contract); 1116 (fraud); 1117 (error); 1159, 1150, 1151 (damages for inexecution of an obligation).

Civil Code of the Province of Quebec Articles 1053 (delict); 1065 (contract); 993 (fraud); 1000 (error); 1073, 1074, 1075 (damages for inexecution of an obligation).

"Anson", *ibid*., pp. 226-258.

J.G. Fleming op. cit., note 23, at pp. 164-169, pp. 616-634 who says (at p. 167) that negligent words giving rise to *physical* (as compared with economic) injury, have long been recognized as a source of liability at Common Law and, further, that a failure to warn (see duty to inform of risks *supra*, p. 12 *et seq*.) may be a negligent misrepresentation.

355. For a case where a deceit action was taken against a doctor see *Hedin v. Minneapolis Medical & Surgical Institute* 62 Minn. 146, 64 N.W. 158 (1895).

For a discussion of deceit by medical practitioners see A.R. Holder, *op. cit*., note 54, at p. 345.

Also see The Canada Council, "Report of the Consultative Group on Ethics", *supra*, note 248, at p. 15, which states that deception may amount to the criminal offence of false pretences if it is done for gain at the subject's expense.

356. See The Canada Council, "Report", *ibid*.

Seeing deception as ethically objectionable because it infringes human dignity, relates to the value of autonomy, and possibly to that of inviolability, if waiver of the latter depends on *informed* consent and this is not considered present even if one consents to be deceived. It does seem, however, that one can validly waive the right to inviolability without "informed" consent in the full sense, as one can choose not to be informed in a therapeutic situation, and also the "therapeutic privilege" of the doctor operates outside "informed" consent without transgressing the right of inviolability, although this privilege may alternatively be regarded in the light of justifying the transgression of inviolability that does occur.

357. M. Mead, "Research with Human Beings: A Model Derived from Anthropological Field Practice", in "Freund ed.", *op. cit.*, note 6, p. 152, at pp. 166-8.

358. See also S. Bok, "The Ethics of Giving Placebos", Scientific American 231 (15) 17 (1954), at p. 19, who argues that doctors who deceive for therapeutic reasons become progressively more used to employing deception and therefore extend its use.

359. *Supra*, note 248, at p. 16.

See also Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at pp. 23-24, where it is stated that the use of deception requires, 'inter alia', "scientific justification of the highest order", that the risk of the research must be "negligible", and that the subject must be debriefed.

360. Is a consent to being deceived the same as consent to information being withheld? Even if these represent the same reality, the language of the former would put the subject more on notice of that to which he was consenting.

361. E.D. Pellegrino, *supra*, note 327, at p. 316.

362. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 70.

Note the Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at p. 24, does not require such information to be destroyed, but that the deceived subject's wishes regarding the use of the data be respected and if he declines it must not be used.

363. C. Fried, *op. cit.*, note 9, at p. 102.

364. Office of Science & Technology "Privacy and Behavioural Research", Washington D.C.; U.S. Government Printing Office, 1967. Reprinted in part in "Katz ed.", *op. cit.*, note 3, at p. 729.

365. T. Parsons, *supra*, note 203, at p. 140.

366. See G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 35.

367. O.M. Ruebhausen and O.G. Brim, "Privacy and Behavioural Research", (1965) 65 Columbia Law Rev. 1184, at p. 1197.

368. See *supra*, pp. 20-21.

369. O.M. Reubhausen and O.G. Brim, *supra*, note 367, at p. 1186.

See also M. Ouellette-Lauzon, "Chroniques Régulières. Le droit à l'image", (1974) 34 Rev. du Barreau (Québec) 1.69, who says: "La doctrine a reconn|u| que tout individu a le droit, entre autres, à son honneur, à son image, à sa "sphère d'intimité" (right to privacy)".

370. *Supra*, note 248, at p. 23.

371. This may be described as the conflict of privacy and progress. See the statement of the United States Office of Science & Technology, "Privacy and Behavioural Research", *supra*, note 364.

372. See L. Dérobert, "Droit Médical et Déontologie Médicale", Paris; Flammarion Médecine-Sciences, 1974, at pp. 249-58; G. Boyer Chammard and P. Monzein, *op. cit.*, note 56, at pp. 216-30.

373. I. Berlin, *op. cit.*, note 184, at p. 129.

374. *Pavesich v. New England Life Insurance Co.* 122 G.A. 190, 193-198; 50 S.E. 68, 69-71 (1905), per Cobb J..

375. See P. Lombard *et al*, *op. cit.*, note 78, at pp. 171-216, who trace the history and jurisprudential development of the obligation of medical secrecy in French Law and who say the "ancien droit" did not recognize such an obligation, but that it developed with 19th century individualism and, further, that now, with socialized and collective medicine, it is retracting.

376. "Universal Declaration of Human Rights" Adopted and proclaimed by the General Assembly of the United Nations 10th Dec., 1948, O.R. Third Session Gen. Assl, Doc. A/810, Article 12.

377. "Declaration of Geneva. Medical Vow", Adopted by the General Assembly of the World Medical Association at Geneva, Switzerland, September, 1948. Amended by the 22nd World Medical Assembly, Sydney, Australia, August 1968. Reprinted in "Katz ed.", *op. cit.*, note 3, at p. 312.

378. *Privacy Act* S.B.C. 1968, c. 39, as amended by S.B.C. 1975, c. 37.

379. *Privacy Act* S.M. 1970, c. 74, as amended by S.M. 1971, c. 23.

380. 1977, 25-26 Eliz. II, c. 33, section 2(b) and Part IV.

381. *Ibid.*, section 2(b).

382. *Ibid.*, Part IV.

383. *Ibid.*, section 50.

384. *La Charte des Droits et libertés de la Personne* L.Q. 1975, c. 50, Article 1.

385. *Ibid.*, Article 5.

386. *Ibid.*, Article 49.

387. *Ibid.*

388. Second edition (2nd Reprint), June 1976. Ratified by Decree No. 3391, Oct. 6, 1971.

389. *Ibid.*, at section 52, Article 20.

390. See for example: *Griswold v. Connecticut* 381 U.S. 479 (1965); *Roe v. Wade* 410 U.S. 113 (1973), at p. 154; *Stanley v. Georgia* 394 U.S. 557 (1968); *Eisenstadt v. Baird* 405 U.S. 438 (1972); Cf. *Doe v. Cwths. Attorney* 90 S.Ct. 1439 (1976); H.P. Green and A.M. Capron, *supra*, note 271, at p. 71, say there are two groups of rights associated with the constitutional right to privacy, as developed by the United States Supreme Court. These are: rights relating to marriage and procreation; and rights of control over one's own body. Both categories are relevant to medical treatment and research considerations.

391. "American Medical Association. Ethical Guidelines for Clinical Investigation". Published by the American Medical Association, 535 North Dearborn St., Chicago, Illinois 60610.

392. British Medical Association (B.M.A.), "Medical Ethics" London, 1974, at p. 13.

393. Statement by the Medical Research Council, *supra*, note 251.

394. See, for example: A.R. Holder, *op. cit.*, note 54, at p. 265; H.P. Green and A.M. Capron, *supra*, note 271, at p. 63.

395. See: *Saltman Engineering Co. Ltd. v. Campbell Engineering Co. Ltd.* [1963] 3 All E.R. 413 n.; *Seager v. Copydex Ltd.* [1967] 1 W.L.R. 923; *Seager v. Copydex* (No 2) [1969] 1 W.L.R. 809; *Argyll v. Argyll* [1965] 1 All E.R. 611, where the jurisdiction to award an injunction preventing a breach of confidence was founded on a general "policy of the law" (at p. 625); "Winfield and Jolowicz", *op cit.*, note 166, at pp. 493-4; A.R. Holder, *ibid.*, p. 271.

Breach of confidence may give rise to an action for breach of fiduciary duty, as well as an action within the area of intentional torts as suggested by Holder.

See also W. Prosser, *op. cit.*, note 16, at pp. 812-814, who speaks of a tort of placing a person in a "false light in the public eye", which need not necessarily be defamatory. Where there is some inaccuracy in a disclosure, which is also a breach of confidence, this tort could be considered as well.

396. H.P. Green and A.M. Capron, *supra*, note 271, at p. 63.

397. See J.G. Flemimg, *op. cit.*, note 23, at pp. 122-133; H.P. Green and A.M. Capron, *supra*, note 271, at p. 62; N. Hershey and R.D. Miller, *op cit.*, note 63, at p. 147.

398. *Michigan Stats. Ann.* Section 14-533.

See also *The Professional Standards Review Organization Act* 42 U.S.C. § 1320c-c-19 (Supp. II, 1970) at § 1320c-15a, which legislates a duty of confidence for doctors treating patients pursuant to the provisions of this Act and which carries a penalty for breach of this duty of six months imprisonment, or a $(US)1,000 fine.

399. Article 7 *Code de Déontologie médicale* (France), *supra*, note 72.

400. Article 378 *Code pénal* (France).

401. Most of the categories which I describe here as exceptions J.R. Waltz, *supra*, note 93, at p. 151, lists as defences to an action against a doctor for invasion of privacy.

402. G. Levasseur, "La responsabilité pénale du médecin", in "Eck ed.", *op. cit.*, note 246, p. 133, at p. 146, says there is a conflict in French Law whether a doctor must testify as to medical secrets. Levasseur is of the opinion that the doctor is justified in not doing so.

403. A.R. Cross, "Evidence", 4th ed. London: Butterworths, 1974, at p. 258, makes reference to both the English and American Law on medical privilege; H.P. Green and A.M. Capron, *supra*, note 271, at p. 62, citing *AB v. CD* Sess. Cas. (Dunlop) 2d. Ser. 177 (1851) say English and United States Common Law gave little protection of the medical secret; A.R. Holder, *op. cit.*, note 54, at p. 271; R.J. Levine, "Guidelines for Negotiating Informed Consent with Prospective Subjects of Experimentation", Clinical Research 22:42 (1974), at p. 45, says the State of Connecticut does not recognize medical privilege except if a psychiatrist is involved and even then the privilege is limited.

404. See J.R. Waltz, *supra*, note 93, at p. 150; H.P. Green and A.M. Capron, *ibid.*; *Cf.* L. Dérobert, *op. cit.*, note 372, at p. 260, who says that the professional secret is "d'ordre public".

405. See O.M. Ruebhausen and O.G. Brim, *supra*, note 367, at p. 1209.

For legislation of this privilege in relation to specific medical research situations, for example research on drug or alcohol abuse, see N. Hershey and R.D. Miller, *op. cit.*, note 63, at pp. 113-122.

406. L. Portes, *op. cit.*, note 235, at pp. 161-3.

407. See British Medical Association, "Medical Ethics" *supra*, note 392, at pp. 17-18.

408. See *supra*, p. 13 and note 62, for a discussion of "therapeutic privilege" and *supra*, p. 26 *et seq.*, for comments on the duty to give a patient access to his medical records or disclose results to him.

409. B.L. Kaiser, "Patients' Rights of Access to their Own Medical Records: The Need for New Law", (1975) 24 Buffalo Law Rev. 2:317.

410. See British Medical Association, "Medical Ethics", *supra*, note 392, at p. 13, which states this duty generally in the following terms: "rarely, the public interest may persuade the doctor that his duty to the community may override his duty to maintain his patient's confidence".

Also see American Medical Association, "Opinions and Reports of the Judicial Council", Illinois; 1972, at Section 9, p. 43, which states the doctor may reveal confidence entrusted to him in the course of medical attendance if the welfare of the individual, or the *community*, requires it.

H.A. Davidson, "Legal and Ethical Aspects of Psychiatric Research", Am. J. Psych. 126(2) 237 (1969), at p. 239 describes the latter part of the exception regarding the community, as a loophole in confidentiality.

The Canada Council, Report of the Consultative Group on Ethics, *supra*, note 248, at p. 29, also recognizes that in exceptional circumstances there may be reasons of public safety overriding a duty of confidentiality.

L. Dérobert, *op. cit.*, note 372, at p. 262, says there may be certain derogations from medical secrecy to preserve society.

411. See R. Macklin, "Ethics, Sex Research, and Sex Therapy", The Hastings Center Report 6(2) 5 (1976); G.J. Annas, "Problems of Informed Consent and Confidentiality in Genetic Counseling", in "Milunsky and Annas eds.", *op. cit.*, note 62, p. 111, at p. 119, says there are some legal precedents in the United States that a doctor has a duty to warn others, even if this is a breach of confidentiality.

412. See the discussion on Huntington's Chorea, *supra*, p. 26 and note 152; *Cf.* J.R. Waltz, *supra*, note 93, at p. 150, who says there may be stigmatization of the individual by breach of privacy in genetic screening so that one is in a situation where to disclose will harm the individual, additionally to the harm comprised *per se* in the breach of his right of privacy, and not to disclose, will harm others; Mahoney, "Discussion" (*inter alia* of Waltz' paper, *ibid.*, in "Milunsky and Annas eds.", *supra*, note 62, at p. 192) suggests one way to overcome this difficulty may be to develop a legal notion of the family as a unit of confidentiality for genetic information rather than the individual.

413. Statement by the Medical Research Council (United Kingdom), *supra*, note 251.

414. See for example: *Loi 15 fév 1902* (France), cited by L. Kornprobst, "Du secret professionnel médical", in "Eck ed.", *op. cit.*, note 246, p. 39, at p. 48, and by L. Kornprobst and S. Delphin, *op. cit.*, note 62, at No. 367; *Décret 29 janv. 1960*, as modified by *décrets 20 mai 1964* and *27 nov. 1968* (France).

Articles 259 and 662 *Code de la santé publique* (France).

415. *Washington Research Project Inc. v. D.H.E.W.* 504 F. 2d. 238, *cert. denied* 421 U.S. 963 (1975).

In general, medical files are exempted from the operation of the provisions of the *Freedom of Information Act* 5 U.S.C. § 552, on the basis of personal privacy.

416. *Ibid.*

417. See for example: Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at pp. 26-27; Statement by the Medical Research Council (United Kingdom), *supra*, note 251; Canada Council, Report of the Consultative Group on Ethics, *supra*, note 248, at p. 28.

Query the effect of the D.H.E.W. Regulations in this respect 45 C.F.R. § 46.119(b): "except as otherwise provided by law, information in the records or possession of the institution acquired in connection with [research] . . . which information refers to or can be identified with a particular subject, may not be disclosed except: (1) with the consent of the subject or his legally authorized representative; or (2) as may be necessary for the Secretary to carry out his responsibilities under this part". It is not clear what "refers to" means, whether it just means is referable to a subject in a general sense, or that it "refers to", in the sense of names, the subject. In view of the inclusion of the alternative provision regarding identification, which would otherwise be superfluous, and the use of the word "particular" to qualify "subject", I suggest the latter, more limited interpretation is the correct one, and therefore some epidemiological research could be conducted without consent.

Cf. the interpretation of the D.H.E.W. Regulations by N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 36. They believe a physician must even ask a patient's consent to giving the patient's name to a researcher as a possible subject, that is the patient must consent to being approached, and that the same rules apply to any use of the patient's records.

Cf. O.M. Reubhausen and O.G. Brim, *supra*, note 367, at pp. 1196-7, who argue that consent and anonymity are not alternative, but cumulative, requirements, that is that one needs consent to have access to the information and anonymity in using it.

418. Note that there is legislation relevant to some presentations at scientific meetings in Quebec, see *An Act to Amend the Public Health Protection Act* Bill No. 88 assented to 27th June 1975, Third Session, Thirtieth Legislature, National Assembly of Quebec, section 10, adding Article 37a *Public Health Protection Act* which provides that: "No person may present or allow the presentation, for *other than educational or scientific purposes*, of a show or exhibition in which the feeblemindedness or mental illness of a human being

who personally appears in the show or exhibition is put on display or exploited, or act as organiser of such a show or exhibition". (Emphasis added)

419. See American Medical Association, "Opinions and Reports of the Judicial Council", *supra*, note 410, at section 9, p. 52; L. Kornprobst and S. Delphin, *op. cit.*, note 62, at No. 395.

Also see *Rebeiro v. Shawinigan Chemicals (1969) Ltd.* [1973] C.S. 389 (Quebec), where it was held that a photograph taken of the claimant could not be used by the defendant without the claimant's consent in general terms, if it could embarrass the claimant.

420. I refer here more to publication by writing, as if the publication involves a presentation which requires active participation by the patient, as at a scientific meeting, consent will be expressed or implied, provided the patient has the required capacity to consent.

421. L. Kornprobst, *supra*; note 414, at p. 99, says that in France this exception is based on "usage", which still does not inform one whether or not the foundation of the custom is implied consent.

It appears that in the United States the patient's consent to publication or discussion of his case must be obtained, even if anonymity is preserved. See A.R. Holder, *op. cit.*, note 54, at pp. 272-6, and *Bachrach v. Farbenfabriken* 344 N.Y.S. 2d. 286 (N.Y. 1973)

422. See: A Report of a Task Force established jointly by the Department of Communications and the Department of Justice, "Privacy and Computors", Ottawa; Information Canada, 1972; Medical Reearch Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at pp. 26-27.

423. See J.K. Wing, *supra*, note 265, who refers to a document of the Royal College of Psychiatrists (England), on confidentiality of information collected by information systems

"Editorial" Med. J. Aust. 1973.2.1022, reporting on the 27th World Medical Association Assembly, Munich, which was held to discuss problems of confidentiality associated with computors in medicine

World Health Organization, "L'élément santé dans la protection des droits de l'homme", Chronique O.M.S. 30:391 (1976), at p. 400, reporting on 27th W.M.A. Assembly, as above.

424. See J.A. Baldwin *et al*, *supra*, note 251, at p. 419.

425. *Ibid.*, at p. 421.

426. C. Levine, "Sharing Secrets: Health Records and Health Hazards", The Hastings Center Report 7(6) 13 (1977), at p. 15.

427. D.J. Whalan, "Protection of Privacy has become Pressing", The Australian Financial Review June 24th 1969, at p. 36. Referred to by H.H. Dickenson, "Medical Ethics and the Law. The Position of the Medical Administrator", Med. J. Aust. 1970 1(16) 794.

428. Cited *supra*, note 380.

429. *Ibid.*, section 2(b).

430. *Loi sur les services de santé et les services sociaux*, cited *supra*, note 281, section 7.

431. *Ibid.*

432. P. Lombard *et al*, *op. cit.*, note 78, at p. 192.

433. G. Boyer Chammard and P. Monzein *op. cit.*, note 56, at p. 133.

434. L. Kornprobst and S. Delphin, *op. cit.*, note 62, at No. 372.

435. See *Barber v. Time Inc.* 348 Mo 1199; 159 S.W. 2d 291 (1942).

436. J.A. Baldwin *et al*, *supra*, note 251, at p. 418.

437. See for example: *Professional Standards Review Organisation Act*, cited *supra*, note 398.

See also the formerly proposed and now lapsed Australian legislation, *National Compensation Bill 1974*, which is analyzed section by section by H. Luntz, "Compensation & Rehabilitation", Melbourne; Butterworths, 1975. This would have enacted (at section 103) a statutory duty of confidentiality, of what would be primarily medical information, binding on all "officers", a much broader group than just medical practitioners.

438. See "Report and Recommendations Psychosurgery. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research", D.H.E.W. Publication No. (OS) 77-0001, U.S. Gov't. Printing Office, Washington, D.C., 1977, at pp. 57, 59-60; *Aden v. Younger* 129 Cal. Rptr. 535 (Ct. App. 4th Dist. Div. 1, 1976).

439. See G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 231, who report that a "Task Force" on psychosurgery, appointed by the Massachusetts Commissioner of Mental Health, split on the issue of whether consent of the proposed patient for psychosurgery should be reviewed by interviewing the patient before a multidisciplinary committee. *All physicians* on the "Task Force" vigorously objected to such review; *Aden v. Younger ibid*. And also as discussed in Annas, Glantz and Katz, at pp. 226-8.

440. G.B. Forbes, "Marginal Comments: Ethics and Editors", American Journal of Diseases of Children 127(4) 471 (1974), at p. 472.

441. This would overcome the undesirable situation with respect to confidentiality, exposed by J.P. Tupin, "Ethical Considerations and Behaviour Control", Tex. Rep. Biol. & Med. 32(1) 249 (1974) at p. 255, where a prison psychiatrist had all his confidential records confiscated and a court held that they belonged to the institution. In such circumstances a prisoner will be less likely and willing to disclose information which could be significant to his medical or psychological treatment.

442. See J.A. Baldwin *et al*, *supra*, note 251, at pp. 421-25.

443. See O.M. Ruebhausen and O.G. Brim, *supra*, note 367, at p. 1206, who say in default of such consents the data must be destroyed.

Cf. the suggestion made with regard to deception, *supra*, p. 56, of giving a copy of the information to the patient but otherwise destroying it, if the patient does not subsequently consent to its retention and use. This could also be done where deception is not involved, but the patient has not consented to the use

or retention of information prior to its being collected and subsequently refuses consent.

444. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 36.

445. See for example *Iowa Code Ann.* § 204.504 (Supp 1975); *Cal. Health & Safety Code* (1975) § 11603; *Cal. Welf & Inst Code* § 5328 (Supp 1975); *Pa. Stat. Ann Tit.* 71, 1690.104 (Supp 1975); *Illinois Ann. Stat.* Ch. 51 (1966) § 101, § 104.

446. T. Parsons, *supra*, note 203, at p. 140, suggests this in very convulated and complicated language, such that it is extremely difficult to determine exactly what he means by his statement, which appears to be to this effect.

See also United States National Commission, "Disclosure of Research Information under the Freedom of Information Act", *supra*, note 160, at p. 7-9.

447. See O.G. Ruebhausen and O.M. Brim, *supra*, note 367, at p. 1186; J.W. Symington and T.R. Kramer, "Does Peer Review Work?", American Scientist 65(1) 17 (1977), at p. 19.

448. J.S. Baldwin *et al*, *supra*, note 251, at p. 418.

449. The term "incompetent" is used in a very general sense here and is intended to include any person who needs special protection of the law in relation to consent to a medical contract or medical care, because of factual or legal disability or incapacity.

450. See for example: Article 1124 *Code Napoléon* (France); Articles 290, 985, 986, 1029 *Civil Code of the Province of Quebec; "Anson", op. cit.*, note 227, at pp. 196-225; "Cheshire & Fifoot", *op. cit.*, note 288, at pp. 401-430.

451. See *supra*, pp. 35-37.

452. See *supra*, pp. 30-31.

453. See *supra*, pp. 48-49.

454. See for example *Karp v. Vooley and Liotta*, cited *supra*, note 97, where an artificial heart was transplanted into the patient.

455. This effect may arise from decreased intellectual facilities due to illness, or drugs used for pain relief or treatment, or from the effect the knowledge that they are dying may have on some persons. A.M. Capron, *supra*, note 8, at p. 387, says that dying patients may become "pliant experimental subjects" from a fear of abandonment by the doctor if they refuse consent, which fear is particularly acute in the dying.

456. Public Health Council of the Netherlands Report on Human Experimentation, at § 6h. Summary published in 4 World Medical Journal 299 (1957); or W.J. Curran and E.O. Shapiro, *op. cit.*, note 68, at p. 889; and in "Codification and Principles", "Ladimer and Newman eds.", *op. cit.*, note 10, p. 154.

457. M.D. Eilenberg *et al*, *supra*, note 255.

458. W.J. Carran, *supra*, note 63, at pp. 427-8.

Other authors advocating that the dying should not be used as subjects of medical research include: E. Tesson, "Moral Reflection", in "Flood ed.", *op. cit.*, note 73, at p. 109; M.H. Pappworth, *op. cit.*, note 308, at p. 78; H.K. Beecher, "Experimentation in Man", in "Ladimer and Newman eds.", *op. cit.*, note 10, p. 2, at p. 8.

459. H.K. Beecher, *ibid.*, at p. 17.

460. See, for example, A. Mayrand, *op. cit.*, note 43, at No. 111.

461. The United States: *Uniform Anatomical Gift Act,* cited *supra*, note 283.

Common Law Canada: *Pro forma Human Tissue Gift Act*, cited *supra*, note 283.

Quebec: Articles 21 and 22 *Civil Code of the Province of Quebec*, provide a "contracting-in" and modified "contracting-out" system.

England: *Human Tissue Act*, cited *supra*, note 283, a "contracting-in" system.

462. France: *Caillavet Law*, *supra*, note 35.

Australia: Law Reform Commission (Australia) Report, *supra*, note 283, *Draft Bill* section 25, which provides for both "contracting-in" and "contracting-out", but the basic presumption chosen is the latter.

See also "Report of the Special Committee on Organ Transplantation", BMJ 1970, 1, 750.

463. *The Human Tissue Gift Act*, S.O. 1971, c. 83, section 4(1) (Ontario).

464. See, for example: "Bar Council Report on Organ Transplants", BMJ 1971.3.716; Editorial, "Determination of Death", The Lancet 1970, I, 1092.

None of the "organ transplant legislation" referred to in notes 461-3 above, legislates a definition of death. However, the Law Reform Commission of Australia has proposed a definition in its Draft Legislation, "*Transplantation and Anatomy Ordinance 1977*", Part III, Donations of Tissue after Death, cited *supra*, note 283, at section 42: "A person has died when there has occurred:

(*a*) irreversible cessation of all function of the brain of the person; or
(*b*) irreversible cessation of circulation of the blood in the body of the person."

Some States in the United States have definitions of death. These include Kansas: *Kan. Stat. Ann.* § 77-202 (Supp. 1973); Maryland: *Md. Ann. Code* at 43 § 54 F (Supp. 1973); Connecticut: *Conn. Gen. Stat. Ann.* § 19-139 (Supp. 1973).

Also see "Notes 'Sale of Human Body Parts'", Michigan Law Rev., *supra*, note 274; J.F. Leavell, "Legal Problems in Organ Transplants", (1973) 44 Mississippi Law J. 5.865, at p. 880.

See in particular: H.L. Hirsh, "Brain Death — Medico Legal Status", Southern Med. J. 69(3)286 (1976), which includes a most comprehensive list of references on this topic, available on request from this author.

For discussion of the legislation currently applicable in France, with respect to determining death, which legislation is not really a definition of death, but rather lists a series of tests on the results of which a doctor may conclude death has occurred, see: "Critères de la mort et greffes d'organes", Cahiers Laennec No. 3, Sept. 1970; R. Nerson, *supra*, note 48, at p. 668; J. Malherbe, "Médecine et Droit Moderne", Paris; Masson, 1969, at p. 41 *et seq.*; R. Savatier, "Les Problèmes Juridiques des Transplantations d'organes humains". J.C.P. 1969. I.2247; J. Savatier, "Et in hora mortis nostra: Le problème des greffes d'organes prélevés sur un cadavre". D.1968.89; P.-J. Doll, *supra*, note 36.

These French laws are *Décrets* 3 Déc 1941, 20 Oct 1947, 27 Jan 1955; *Loi* 7 Juillet 1949; *Circular* No. 67, 24 Avril 1968; *Bull.* 21 Fév. 1968.

See also: "Declaration of Sydney. Statement on Death". Adopted by the 22nd World Medical Assembly, Sydney, Australia, August, 1968.

465. See M. Houts and J. Hunt, 1 Death § 1.03 (1970). Quoted by J.F. Leavell, *ibid.*, at pp. 887-8, f.n. 94.

466. Note that requiring different safeguards for different purposes is not the same as defining death differently for different purposes. The Law Reform Commission of Australia in its "Report", *supra*, note 283, at p. 59, No. 127, expressly rejected defining death for only one purpose, in this case transplantation.

467. For a relevant statement of this general legal principle see Statement by the Medical Research Council (United Kingdom), *supra*, note 66.

See also G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at pp. 68-70, who cite *Lacey v. Laird* 166 Ohio St. 12, 139 N.E. 2d. 25, 30 (1956), to the effect that any rule that a minor cannot consent to medical treatment is not based upon determination of his factual capacity to consent, but upon the right of parents whose liability for support and maintenance of their child may be greatly increased by an unfavourable result from medical procedures. Thus a parent has at least some right to withhold consent and, as a corollary, some right to consent. It is worth stating the right in this way, as it shows it is not an unlimited right to consent, or to withhold consent, and the question then becomes what are the limits?

468. See: Lord Kilbrandon, "Chairman's Closing Remarks", in "Wolstenholme and O'Connor eds.", *op cit.*, note 315, p. 212; D. Louisell, *supra*, note 315, at pp. 84-5; A.R. Holder, *op. cit.*, note 54, at p. 17; L. Kornprobst, *supra*, note 246.

Also see "La Charte du Malade hospitalisé" (France), *Décret 14 janv. 1974*. Extracts published in *La Nouvelle Presse Médicale*, 3(5) 265 (1974) at p. 266. Published in full in "La responsabilité civile des médecins", *op. cit.*, note 140, at p. 127, which provides that where a parent refuses consent "le ministère public" can be approached for the authorization; *Child Welfare Act* R.S.O. 1970 c. 64 section 20 (Ontario) under which the State can authorise treatment necessary for the health or well-being of a child; *Medical (Blood Transfusion) Act* 1960 Victoria (Australia), which allows a Court to override a parent's refusal of an operation on a child.

468a. For 'pro forma' legislation of this type recommended for adoption by all Canadian provinces, see Proceedings of the Fifty-seventh Annual Meeting of

the Uniformity Law Conference of Canada, August 1975, *Medical Consent of Minors Act* Appendix N.

469. *Loi de la protection de la santé publique*, L.Q. 1972, c.42, at Article 36.

470. For example in the State of N.S.W. *Minors (Property & Contracts) Act*, Act No. 60, 1970 N.S.W. section 49.

471. *Public Hospitals Act* R.S.O. 1970 c.378 as amended, Ontario Rev. Reg. 729, Ontario Reg. 100/77 §§ 49, 49a.

472. *Infants Act* R.S.B.C. 1960 c.193 as amended by *Act to Amend the Infants Act* S.B.C. 1973 (1st Sess.) c. 43, section 23.

473. *Family Law Reform Act* 1969 17 & 18 Eliz. II c. 46, section 8.

474. For a comprehensive chart setting out the nature and extent of this legislation, in each of the States of the United States, see H.F. Pilpel, "Minor's Rights to Medical Care", (1972) 36 Albany Law Rev. 462.

475. See, for example, the Regulations made under the *Public Hospitals Act* (Ontario), cited *supra*, note 153.

476. Cited *supra*, note 473, at section 8(3).

477. Article 36, *Public Health Protection Act*, cited *supra*, note 469.

Note that the Quebec statute includes an exception allowing for authorization of treatment by a judge of the Superior Court, when consent of the person exercising paternal authority cannot be obtained, or is refused and this is contrary to the child's best interests.

Also note that in view of the recent change from paternal to parental authority in the Civil Code. (see *An Act to Amend the Civil Code*) Bill 65, assented to 17 November 1977, 31st Legislature 2nd Sess., Assemblée Nationale du Québec, and in particular Article 9 of this Act, paternal authority is to be interpreted in the more general sense of parental authority in all statutes and subordinate legislation.

478. R. Dierkens, "Les droits sur le corps et le cadavre de l'homme", Paris; Masson, 1966, at No. 5, p. 43.

Also see L. Kornprobst, *op. cit.*, note 12, at p. 240, and f.n. 7.; *Cf.* H. Anrys, "La Responsabilité Civile Médicale", Bruxelles, Maison Ferdinand Larcier, 1974, at No. 56, p. 84, who argues parental consent is always necessary.

Note that in French Law, pursuant to Article 1124 *Code Napoléon*, minors have no capacity to contract, which, if one accepts that they can consent to medical treatment as some of the jurists quoted suggest, further supports the notion of the dual consent (see *supra*, pp. 35-37) and that the capacity needed for each consent is not the same.

CF. Article 986 *Civil Code of the Province of Quebec*, where minors are not subject to a general incapacity but are only legally incapable of contracting "in the cases and according to the provisions contained in th[e] code". Thus, arguably, in Quebec a minor could both enter a medical contract and because of the statutory provision (*supra*, note 477), provided he was at least fourteen years old, he could also consent to medical treatment.

Also see P. Chassagne, "Risques médicamenteux et responsabilité médicale", in "Eck ed.", *op. cit.*, note 246, at p. 349; P. Lombard *et al*, *op. cit.*, note 78, at p. 162.

479. P.A. Crépeau, *supra*, note 165, at p. 252.

480. Article 36 *Public Health Protection Act*, cited *supra*, note 469.

481. *Cf.* J.-L. Baudouin, *op. cit.*, note 339, at No. 109, who argues the legislative scheme governing minors under Quebec law is a protection taking "la forme d'une incapacité d'exercice quasi générale".

Cf. Dixon v. U.S. 197 F. Supp. 803 (W.D.S.C. 1961), where the Court said that the disability of a minor is a privilege to be exercised for his benefit the object being to protect him from damaging himself or being imposed on by others.

482. P.-A. Crépeau, *supra*, note 165, at p. 252.

483. In fact the statement by P.-A. Crépeau is more definitive than Article 36, which does not expressly require that the minor be capable of discernment, although the necessity for this is implied in requiring that the minor must "consent".

484. Co. Littleton 172a.

485. (1610) 1 Bulst. 39.

486. This is commonly referred to as the "mature minor rule". See: H.L. Nathan, "Medical Negligence; being the law of negligence in relation to the medical profession and hospitals", with the collaboration of A.R. Barrowclough, London; Butterworths, 1957, at pp. 171-179; *Johnston v. Wellesley Hospital* (Ont. H.C.), cited *supra*, note 62, at pp. 144-5, where the Court states that: "The Common Law does not fix any age below which minors are automatically incapable of consenting to medical procedures. It all depends on whether the minor can understand what is involved in the procedure in question".; G.S. Sharpe, "The Minor Transplant Donor", (1975) 7 Ottawa Law Rev. 85, at p. 86; W.F. Bowker, *supra*, note 78, at p. 172; P.D.G. Skegg, "Consent to Medical Procedures on Minors", (1973) 36 Mod. Law Rev. 370, at p. 375; G.E. Railt, "The Minors Right to Consent to Medical Treatment. A Corollary of the Constitutional Right of Privacy", (1975) 48 S. Calif. Law Rev. 6:1389, argues on quite a different basis that, in the United States, a child has a right to consent to medical treatment arising from its constitutional right to privacy, as established for all citizens in *Roe v. Wade*, cited *supra*, note 390. Presumably a right to privacy increases in scope with increasing maturity and hence at a younger age one may more readily interfere with, or override it.

See also American Law Institute, "Restatement of the Law", Torts 2d, 1965, § 59, which allows a child capable of understanding the serious character of an operation for his benefit to consent to it.

For application of the "mature minor rule" by American Courts see: *Bach v. Long Island Hospital* 49 Misc. 2d 207 (N.Y. Sup. Ct. 1966); *Gulf & S.I.R. Co. v. Sullivan* 119 So. 502 (Sup. Ct. Miss. 1928); *Lacey v. Laird* cited *supra*, note 467.

487. W. Wadlington, "Minors and Health Care: The Age of Consent", (1973) 11 Osgoode Hall Law J. 1.115, at p. 124.

488. However as the situation involved is, by definition, one of necessity, the doctor operating on such a minor would be protected from legal action by either a defence of necessity, or implied consent of the patient, or parent, to the operation. See P.D.G. Skegg, *supra*, note 17, at p. 512, who says that "there is widespread agreement that in English law a doctor will sometimes be justified, for the purpose of the crime and tort of battery, in performing medical procedures without consent. Judges have made extra-judicial statements to this effect, and doctors are constantly acting in the belief that this is so. However there is not a single reported English decision which has so much as discussed the existence or limits of such a justification".

489. At note 486, *supra*.

490. G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 64 *et seq*.

491. W. Blackstone, "Commentaries on the Laws of England", Oxford; 1776-79, 4 vols., at Book I, 463.

See generally "Of Parent and Child", 446 *et seq*., "Of Guardian and Ward", 460 *et seq*.

492. See for example *Porter v. Toledo Terminal Railway Co.* 152 Ohio St. 463, 90 N.E. 2d 142 (1950); *Centrello v. Basky* 164 Ohio St. 41, 128 N.E. 2d 80 (1955); *Heisler v. Moke* [1972] 2 O.R. 466; *Gough v. Thorne* [1966] 3 All E.R. 398; *McHale v. Watson* (1966) 39 A.L.J.R. 459.

493. See G.J. Annas, L.G. Glantz and B.F. Katz, *op. cit.*, note 63, at pp. 68-70 and discussion at note 467, *supra*.

494. See "Notes 'Sale of Human Body Parts'", *supra*, note 274, at p. 1196.

495. G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 70.

496. See for example L. Kornprobst and S. Delphin, *op. cit.*, note 62, at No. 51.

Note that the N.S.W. *Minors (Property & Contracts) Act*, cited *supra*, note 470, at section 49, raises some potential conflicts in this respect, as it provides that a minor of fourteen years of age or more may consent to medical treatment and that a surgeon is legally protected from proceedings for assault, if a parent or guardian of a minor under sixteen years of age gives consent to medical treatment on such a minor. It would seem that the minor aged between fourteen and sixteen years may consent to, but not refuse, treatment.

497. See U.S. National Commission, "Staff Draft. Research Involving Children Recommendations", 1st April, 1977, at Recommendation 5, p. 13. (Supplied to the writer by the Secretary of the United States National Commission).

The National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research "Report and Recommendations, Research Involving Children", D.H.E.W. Publication No(OS) 77-0004, U.S. Government Printing Office, Washington, D.C., 1977, at Recommendations 7, pp. 12-13. That the right to veto treatment arises before a right to consent is exactly the reverse of the situation under the N.S.W. *Minors (Property & Contracts) Act*, discussed *ibid*.

498. H.F. Pilpel, *supra*, note 474, at p. 462.

See also W. Wadlington, *supra*, note 487, at p. 124.

499. I suggest that in the case of a mature minor, one is probably no more justified in inflicting medical treatment on him against his will, than one would be in the case of a dissenting adult.

500. The Canada Council Consultative Group on Ethics, *supra*, note 248, at p. 35, would allow non-therapeutic research to be conducted on children with the consent of the parents, subject to the child having the right of veto.

Also see U.S. National Commission, "Staff Draft, Research Involving Children, Recommendations", *supra*, note 497, at Recommendation 5, p. 13, and "Report and Recommendations", *supra*, note 497, at Recommendation 7, pp. 12-13.

501. The Medical Research Council (United Kingdom), *supra*, note 60, at p. 179, suggests that depending on the age, intelligence, situation and character of the subject and the nature of the "investigation", a child not below the age of twelve years may be able to consent to non-therapeutic research.

502. The Nuremberg Code (*supra*, note 65), does not allow for "proxy consent" to non-therapeutic research, as it requires legal capacity of the subject to consent. In comparison the Declaration of Helsinki (*supra*, note 69), provides for this, as does the Report of the Canada Council Consultative Group on Ethics, (*supra*, note 248), and the F.D.A. Regulations in the United States (21 C.F.R. § 310.102(b)). The Regulations indirectly mandate research on children, as they specify that before drugs can be approved for marketing for use in children, they must be proved "safe and effective" for that group (21 C.F.R. § 310.6) which necessitates clinical trials on children. What often happens is that the drugs are marketed for adult use, but in practice are used for children.

B.L. Mirkin *et al*, "Panel on Pediatric Trials", Clin. Pharm. & Therap. 18(5).2.657, deplore this haphazard use and suggest that approval for adult use should be contingent on conducting trials in children, where the drug may be used paediatrically.

A. Mayrand, *op. cit.*, note 43, at No. 47, says that in Quebec the legal limit of parental consent is to treatment required by the state of health of the child.

503. Possibly the best concise summary of all these lines of argument is to be found in the United States National Commission, "Report and Recommendations. Research involving Children", *supra*, note 497.

504. See P. Ramsey: *supra*, note 201; "Shall we 'Reproduce'? Pt. I. The Medical Ethics of In Vitro Fertilization", J.A.M.A. 220(10) 1346 (1972); "Pt. II. Rejoinders and Future Forecast", J.A.M.A. 220(11) 1480 (1972); "The Enforcement of Morals: non-therapeutic research on children", The Hastings Center Report 6(4) 21 (1976).

In agreement with Ramsey is W.E. May, *supra*, note 182.

505. For the initial article by R. McCormick see *supra*, note 244; also see *supra*, note 194; and "Foetal Research, Morality and Public Policy", The Hastings Center Report 5(3) 26 (1975).

506. Feasibility is not determinative of ethics, although *cf.* J. Fletcher's "situational ethics", (see "Ethical Aspects of Genetic Controls. Designed Genetic Changes in Man", N.E.J.M. 285(14) 776 (1971); and *supra*, note 62), under which he advocates that all data, which would include feasibility,

should be weighed for ethical decision purposes in each new situation, rather than determining definite principles of right and wrong applicable to all situations. Even if one does not give feasibility ethical weight it must be taken into account at least in legislating, if not in establishing personal, moral precepts.

507. S. Toulmin, "Exploring the Moderate Consensus", The Hastings Center Report, 5(3) 31 (1975), at p. 34.

508. See R. Savatier, *supra*, note 36; R. Dierkens, *op. cit.*, note 477, at p. 31; P.-J. Doll, "L'aspect moral, religieux et juridique des transplantations d'organes", Gaz. Pal. 1974 2. doctr. 820, 28 Sept. 1974.

509. See P.-J. Doll, *ibid.*, at p. 822, who describes such exceptional circumstances as a donor child acting to save a brother, sister, or twin.

510. P.-J. Doll, *ibid.*, reports that on the 14th March, 1961, "La Chancellerie" took account of the consents of a fourteen year old with full understanding, and of his parents, and of the favourable view of the "Conseil National de l'Ordre des Médecins", and gave permission for a transplant of a kidney to his sister, this being the only hope of saving the life of the latter.

511. *An Act to Amend the Civil Code*, cited *supra*, note 477.

512. See *supra*, pp. 71-75.

513. A. Mayrand, *op. cit.*, note 43, at No. 7.

Note that although such a right has been legislated, and special conditions for its exercise imposed in the case of minors, as far as the author is able to ascertain there has never been an application to a Court in Quebec pursuant to Article 20. As there are many active medical research institutions in the Province either the requirements of Article 20 are being ignored, or all research involving children has ceased.

514. See *infra*, p. 81 *et seq.*

515. *Human Tissue Gift Act*, cited *supra*, note 463.

516. *Human Tissue Act*, S.B.C. 1968 c.19; *Human Tissue Gift Act*, S.B.C. 1972, c. 27.

517. *Human Tissue Act*, R.S.N.S. 1967.

518. *Human Tissue Act*, S. Nfld. c. 132, 1971, No. 66.

519. Note tissue is defined to exclude "tissue replaceable by natural process of repair" (see, for example, Ontario *Human Tissue Gift Act* section 1(c)). Presumably the validity of a minor's consent with respect to procedures such as blood donation or other regenerative tissue, therefore depends on the Common Law.

520. Proc. Conference of Commissioners on Uniformity of Legislation in Canada, (1965) 104.

521. P.D.G. Skegg, *supra*, note 486, at p. 375.

522. See: *Re L* [1968] P. 119 (C.A.); *B (BR) v. B(J)* [1968] P. 466 (C.A.); *S. v. McC (McC & W v. W)* [1972] A.C. 24.

523. See: P.D.G. Skegg, *supra*, note 17, at p. 375 *et seq*; B. Dickens, "The Use of Children in Medical Experimentation", (1975) 43 Medico-Legal Journal 166.

524. G. Dworkin, "Law relating to organ transplantation in England", (1970) 33 Modern Law Review 353, at p. 360.

525. Especially if one considers that "best interests" may include "financial interests" of the child — see *S. v. McC*, cited *supra*, note 522, at p. 42, and P.D.G. Skegg, *supra*, note 486, at p. 379. Skegg suggests that *S. v. McC* should be used as a basis for adopting a rule that a parent can consent where a reasonable parent would consent, that is, where it is not against the child's interest and is in the public interest. Such a test would allow a parent to consent to non-therapeutic experimentation on his child. One queries whether dicta handed down within the narrow confines of the question of whether or not a blood test can be inflicted on a child, *for the purpose* of establishing its legitimacy, should be extended to the full scope of non-therapeutic experimentation, especially when such a blood test is authorized by statute (*Family Law Reform Act*, 1969 17 & 18 Eliz. II c.46, section 20) which presumably establishes its basic legitimacy. The same cannot be said with respect to non-therapeutic experimentation on children.

526. 139 A.L.R. 1366 (1941), especially at p. 1369; 126 F. 2d 121 (1941).

527. It is not clear from the judgment in *Bonner v. Moran* (*ibid.*), whether the parents' consent would have been sufficient without the boy's consent. The case may be interpreted as stating that in the non-therapeutic situation the "mature minor" rule only applies if supplemented by parental consent. It is not informative about the situation where the minor is incapable of consent; A.M. Capron, "Legal Considerations Affecting Clinical Pharmacologic Studies in Children", *supra*, note 193, at p. 143, argues *Bonner v. Moran* should not be interpreted as including the implication that parents can consent to non-beneficial treatment on a child, as, he says, the court in that case and subsequent courts have avoided ruling on the question. This is true in cases where the courts found psychological benefit and therefore consent to a *beneficial* procedure, but *cf. Nathan v. Farinelli* (Unreported) Eq. No. 74-87, Mass. July 3, 1976 (Mass U.S.), which is discussed in the text which follows.

528. 289 A. 2d 386 (Conn. 1972).

529. Cited *supra*, note 527.

530. (Unreported) No. J74-57 (Mass. Aug. 28, 1974).

531. 445 S.W. 2d 145 (Ky 1969).

See also *Howard v. Fulton-Dekalb Hospital Authority* 42 U.S.L.W. 2322 (Ga. Sup. Ct., Fulton City, Nov. 29, 1975) where the Court relying on its *parens patriae* power authorized a kidney donation from a fifteen year old "moderately retarded" girl to her mother, taking into account avoidance of the emotional shock which would be caused to the daughter if her mother died, although there was "no intelligent written consent by" the daughter.

532. Note that the Court authorized the donation under its equitable *parens patriae* or "substituted judgment" power, that is its power to act in the *best interests* of a minor or incompetent, and did not support its decision "via" the parents' consent (*ibid.*, pp. 147-9, especially at p. 149). For a full discussion of the substituted judgment doctrine, which is basically premised on a guess at what

the incompetent would choose if competent, see J.A. Robertson, "Organ Donations by Incompetents and the Substituted Judgment Doctrine", (1976) 76 Columbia Law Rev. 48.

533. 284 So 2d. 185 (La App. 1973). Note that here, although it was not significant in the case, the mental incompetent was also a minor.

Also see *Lausier v. Pescinski* 67 Wis. 2d. 4, 226 N.W. 2d. 180 (1975), where the Court expressly held that neither it, nor the guardian of a thirty-nine year old mental incompetent with a mental age of twelve, could substitute their consent for that of the ward, when the procedure involved, kidney donation, was non-beneficial to the latter.

534. See G. Dworkin, *supra*, note 524, at pp. 356-7.

535. See *Strunk v. Strunk*, cited *supra*, note 531, at p. 146.

Also see notes 523 and 525, *supra*.

536. All are unreported, but are referred to in *Hart v. Brown*, cited *supra*, note 528, at p. 387. The cases are: *Masden v. Harrison*, No. 68651, Eq. Mass. Sup. Jud. Ct. (June 12, 1957); *Hushey v. Harrison*, No. 68666, Eq. Mass. Sup. Jud. Ct. (Aug. 30, 1957); *Foster v. Harrison*, No. 68674, Eq. Mass. Sup. Jud. Ct. (Nov. 20, 1957).

537. See W.J. Curran, "A Problem of Consent: Kidney Transplantation in Minors", in "Ladimer and Newman eds.", *op. cit.*, note 10, p. 237, at p. 242; C.H. Baron *et al*, *supra*, note 180, at p. 161, after analyzing these cases come to the conclusion that the Courts did not treat the consents of the parents, or children, involved, as effective. "Instead [in each instance] it heard evidence and decided for itself whether, under the circumstances the operation should be permitted to go forward". If true, this may be explained on the basis that these cases sought declaratory judgments as to "the lawfulness of the procedure" (see D.W. Meyers, "The Human Body and the Law", Chicago, Aldine-Atherton, 1970, at p. 123) and it is possible that the Courts were not so concerned with the issue of consent *per se*, as with banning any future legal action against the doctors.

538. Cited *supra*, note 528.

539. See the comments by G.S. Sharpe, "The Minor Transplant Donor", (1975) 7 Ottawa Law Rev. 85 at p. 98.

540. Cited *supra*, note 527.

541. See G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 89.

542. *Ibid.*, pp. 85-87.

543. A.M. Capron, *supra*, note 193, at p. 146; and *supra*, note 81, at p. 319.

Essentially Capron suggests replacing parental consent by a model of decision-making, that is a decision-making framework, of "successive limited approximations", which narrows down the issues and points the way to alternative safeguards, which include, but are not limited to, parental consent. The steps are: *to limit* the perceived need for the experiment as much as possible; *to limit* the risk; then *to limit* the participants (a) by use of therapeutic experimentation on sick children where possible; (b) if normal children are used by: (1) eliminating institutionalized children; then 2(i)

allowing selection by the guardian; then (ii) selection on the basis of medical and psychological fitness; and then (iii) random choice among those eligible; finally *to limit* damage by on-going monitoring. (Clinical Res. *ibid.*, at pp. 145-7). As Capron goes on to say (*ibid.*, p. 147) the "most uncomfortable feature" of selecting child subjects on the basis of fitness and random choice is the power given to the state.

544. This language has been adopted by the United States National Commission in their "Staff Draft. Research Involving Children. Recommendations", *supra*, note 497, at p. 3, and in "Report and Recommendations", *supra*, note 497, at Recommendation 3, p. 5.

Also see B. Freedman, "A Moral Theory of Informed Consent", The Hastings Center Report 5(4) 32 (1975), at pp. 37-8, who says "proxy consent" given for children is a different entity from consent in adults.

545. United States National Commission "Staff Draft. Research Involving Children. Recommendations", *ibid.*, at p. 14.

See also J. Viret, *supra*, note 150, at p. 915, who says one cannot speak of "un consentement éclairé" of someone other than the patient.

546. "No risk" or "minimal risk" is a difficult concept to define for practical purposes and the United States National Commission ("Staff Draft", *ibid.*, p. 4) suggest that, within the medical research context, it means the research "does not involve any risks or discomforts to children greater than those normally encountered in their daily lives or in routine medical or psychological evaluations . . . " and further (p. 5), that if there is substantial uncertainty regarding the risks, they cannot be considered minimal.

Although it is implied in this statement, if should be clearly recognized that "minimal risk" encompasses both likelihood of the risk eventuating and the magnitude of the harm if it does, that is I am using the term as meaning minimal risk of minimal harm. This draft Recommendation should be compared with the final version, "Report and Recommendations", *supra*, note 497, which substitutes for the separation of risks into no "risks or discomforts . . . greater than those normally encountered in . . . daily li[f]e" . . . and "risks or discomforts greater than th[e]se . . . ", a division of "not . . . greater than minimal risk . . . ", "more than minimal risk . . . ", and "a minor increase over minimal risk . . . " (at Recommendations 3, 4, & 5 respectively). It would seem that the latter classification is broader with respect to risks in the first category, which has less stringent approval requirements, and is probably of wider overall scope as far as allowing research is concerned, as risks falling within the third class are not dealt with as stringently as those within the second group.

Whether parents can ever consent to non-therapeutic research on their children is in issue in *Neilson v. Regents of University of California et al* (Civ. Case No. 665-049 Sup. Ct. of Calif., County of San Francisco filed Aug. 23rd, 1973, as amended Dec. 20th, 1973) which seeks a declaration prohibiting a proposed non-therapeutic, allergenic research project on children, for whose participation the parents would be paid. The case is still pending.

The Royal College of Physicians (United Kingdom), "Code" *supra*, note 67, at p. 2, allows for "proxy consent" to non-beneficial procedures on children and mental incompetents, where there is negligible risk.

Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at pp. 30-31, would also allow such procedures.

547. See Statement by the Medical Research Council (United Kingdom), *supra*, note 66, at p. 179, "that in the strict view of the [English] law parents and guardians of minors cannot give consent on their behalf to any procedures which are of no particular benefit to them and may carry some risks of harm".

Also see Louisiana statutory provision: *La. Stat. Ann* title 14 § 87.2 (1974), which requires consent of the subject of experimentation, with no provision being made for any exception to this.

Cf. New York, *N.Y. Pub. Health Law* § 2441(5) which allows the legal representative to consent to research on the subject incapable of consenting for himself.

547a. It is necessary, to say "arguably" as there is still the objection that consent not only protects against the infliction of unconsented to risk or harm, but also unconsented to role-playing. See *supra* p. 86.

There are also other objections to such a proposal to allow non-consensual "no risk", or "minimal risk", non-therapeutic experimentation on non-discerning children, one being that consent is needed in such circumstances when adults are involved. However, one may be able to distinguish the adult situation from that involving non-discerning children, by arguing that consent is required basically to protect a right to autonomy, which a non-discerning child does not have, and a right or privacy, which has intrinsic and extrinsic features, with only the extrinsic ones being relevant to a non-discerning person and therefore needing protection. Apart from this the duty is to respect the person and protect him from harm, arguably neither of which aspects are contravened by "no risk" experimentation, and the latter only in an insignificant way by "minimal risk" procedures. I prefer such a line of reasoning to recognizing parents' "proxy" consent as effective because of the ramifications of the latter. (See *supra*, pp. 172-173).

This is really to argue that "proxy consent where it is acceptable, which I suggest are McCormick's "ought", or Toulmin's "could not object" situations (*supra*, pp. 161-162) is a legal fiction. Rather the reality is that the same reasoning would apply as where it is argued that consent is not necessary, as in epidemiological research. For examples of the latter see R. Doll, "Obstacles Within the Practice of Medicine: Public Benefit and Personal Privacy; The Problems of Medical Investigation in the Community", Proc. Roy. Soc. Med. 67(12) Pt. 2, 1281 (1974), at p. 1283; Statement by the Medical Research Council (United Kingdom), "Responsibility in the Use of Medical Information for Research", B.M.J. 1973.1.1213.

548. Note that the determination of "no risk", or "minimal risk", must be by an independent body, preferably an ethical review committee.

549. See U.S. National Commission, "Staff Draft. Research Involving Children. Recommendations", *supra*, note 497, at p. 12. "Report and Recommendations", *supra*, note 497, at Recommendation 2, p. 2.

550. A.H. Schwartz, "Children's Concepts of Research Hospitalization", N.E.J.M. 287(12) 589 (1972).

551. For a view relying on a justification other than discernment, for involving children in non-therapeutic research see W.G. Bartholome, "Parents, Children, and the Moral Benefits of Research", The Hastings Center Report 6(6) 44 (1976), who believes it is possible for children aged five to fourteen years to benefit morally from involvement in research and that the parent not only has a duty to protect the child, but also one to enhance his moral development, and therefore such participation by children should be allowed.

552. See the minority position of P.A. Crépeau, Medical Research Council of Canada, "Ethics in Human Experimentation", *supra*, note 69(a), at p. 30.

For a contrary view see: W.J. Curran and H.K. Beecher, "Experimentation in Children: A Re-examination of Legal Ethical Principles", J.A.M.A. 210:77 (1969).

Editorial, "The Ethics of research involving children as controls", Archives of Disease in Childhood (United Kingdom) 1973.48.751, at p. 752.

552a. *Cf.* the position of the majority, in the "Code" of the Medical Research Council, (*ibid.*, at pp. 30-31) that subject to the additional special safeguard of "second level proxy consent" by a "subject advocate or ombudsman" medical research on those unable to consent for themselves may be carried out. Note there is no requirement that the research be of a truly exceptional nature.

553. In support of this approach see: *Kaimowitz v. Michigan Department of Mental Health*, cited supra, note 115, at pp. 197-8, where the court held that the consent of a parent or guardian "is legally ineffective in the psychosurgery situation".

Also see R. Neville, "Pots and Black Kettles: A Philospher's Perspective on Psychosurgery", (1974) 54 Boston Univ. Law Rev. 340, at p. 348, who, speaking of psychosurgery, says there must be strict personal consent and "proxy" consent should only be allowed after adversarial court proceedings. This statement can be generalized so that it applies when the situation is one of a more than minimal risk, non-therapeutic, or doubtfully therapeutic, medical intervention, on any person who is himself incapable of consent.

554. See U.S. National Commission, "Staff Draft. Research Involving Children. Recommendations", *supra*, note 497 at p. 6, which requires for allowing such research, that is more than minimal risk non-therapeutic research on children unable to give "informed" consent, that an institutional review board, a national ethical advisory board, and, after appropriate opportunity for public review, the Secretary of Health Education and Welfare, determine that: the risks are acceptable; a grave health problem generally affecting children exists and such research is the only adequate measure to deal with it; and conditions for assent of the children and permission of the parent as set forth in the recommendations will be met.

See, likewise, "Report and Recommendations", *supra*, note 497, at Recommendation 6, p. 10, which applies similar approval requirements to research that is more than "a minor increase over minimal risk".

555. See H. Jonas, *supra*, note 42.

556. See *infra*, p. 89 *et seq.*

557. *3 Pa. Bull.* No. 2667 (1973). Cited by B. Mishkin, "Multidisciplinary Review for the Protection of Human Subjects in Biomedical Research: Present and Prospective H.E.W. Policy", (1974) 54 Boston Univ. Law Rev. 278, at p. 284.

558. For example in the "Willowbrook Experiments", see *supra*, note 307, parents of mentally handicapped children were told that the only chance of their child being admitted to the institution was if the parent consented to experimentation on the child.

559. *Supra*, note 497.

560. *Supra*, note 497.

561. "Staff Draft. Research on Children", *supra*, note 497, Recommendation 8, p. 22, as amended by the "U.S. National Commission" Meeting June 10-11, 1977, Summary of Minutes Recommendation 9, p. 2.

562. See D.H. Russell, "Law, Medicine and Minors", Pt. IV, N.E.J.M. 279(1) 31 (1968). "Child abuse" legislation can be found in all relevant jurisdictions.

563. *Cal. Penal Code* § 273(a) West 1970. Query if non-therapeutic experimentation is "unjustifiable" within the terms of this Statute. It has been argued in *Nielson v. Regents of University of California*, cited *supra*, note 546, that it is.

564. R.J. Levine, "In Comment . . . ", JAMA 232(3) 259 (1975), at p. 261.

565. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 147.

566. *An Act respecting the protection of children subject to ill-treatment* S.Q. 1974, c.59, section 14j.

566a. It is necessary to distinguish spontaneous and induced abortion as the ethical implications in the former are not the same. The spontaneously aborted foetus would be governed by the same considerations as apply to children or dying or dead subjects, as appropriate.

567. Note that this is the same question as that asked in relation to killing condemned prisoners by medical experimentation, see *infra*, p. 98.

568. Fed. Reg. 8th Aug. 1975, 33546.

Also see T.W. Ogletree, "Values, Obligations and Virtues: Approaches to Bio-Medical Ethics", Journal of Religious Ethics 4(1) 105, 1976, at pp. 111-112, who says that "the National Commission gives special emphasis to the risk of violating the dignity of the foetus as a human subject worthy of protection. Yet if respect for the foetus does not protect it from an abortion decision or from being an unconsenting subject of experimentation, this "risk" cannot meaningfully have as its primary referent the fetus itself. It rather appears to be important chiefly for its bearing upon the moral and psychological well-being of the "parents" and researchers involved in the experimentation, or more generally, for its impact on the moral health of the society which accepts and supports the research". That is, the risk assessed is to others, not to the foetus, with respect to whom the concept of risk is eliminated in substance though not in form, by comparing any possibility of harm to the foetus with the actuality of the situation in which it is placed. One

queries why the National Commission retained such a meaningless concept and I suggest that Ogletree's analysis explains this.

569. Fed. Reg. 8th Aug. 1975, 33528; 45 C.F.R. § 46.209(*d*). This provision requires "informed consent" of the mother and father to research on the aborted foetus, with certain exceptions in the latter case.

570. "The Use of Fetuses and Fetal Material for Research. Report of the Advisory Group", London; Her Majesty's Stationery Office, 1972, (hereafter referred to as the "Peel Report") at p. 8.

571. "Peel Report", *supra*, note 570, at pp. 8-9.

572. *Human Tissue Act*, cited *supra*, note 283.

573. *Ibid.*, at p. 12.

574. *Ibid.*, at p. 9, No. 42.

575. *Ibid.*, at p. 12. Recommended Code of Practice, section 4(1).

576. *Ibid.*, p. 7, No. 32, and see *supra*, pp. 70-71.

577. G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 206.

578. The author, on the basis of personal interviews has reason to believe that this represents the current practice in some Canadian hospitals.

579. R. Wasserstrom, "The status of the fetus", The Hastings Center Report 5(3) 18 (1975), at pp. 20-1.

580. H.O. Tiefel, *supra*, note 135, at p. 88.

581. 45 C.F.R. § 46.206 4(b).

582. *Supra*, note 570, at p. 9, No. 44, and p. 12.

583. See "Report on Injuries to Unborn Children", The Law Commission (United Kingdom) No. 60. Cmnd. 5709 London; Her Majesty's Stationery Office, 1974. *Congenital Disabilities (Civil Liability) Act* 1976 Eliz. II c. 28; *Watt v. Rama* [1972] V.R. 353 (Australia); *Duval v. Seguin* (1972) 26 D.L.R. 3d. 418 (Ontario); *Montreal Tramways Company v. Leveillé* [1933] S.C.R. 456 (Quebec); *Cour d'appel d'Amiens* 28 avril 1964, Gaz. Pal. 1964.2.167.; *Cour d'appel de Paris* 10 janv. 1959, Gaz. Pal. 1959.1.223.; *Bonbrest v. Kotz* 65 F. Supp. 138 (D.D.C. 1946).

See also P.A. Lovell and R.H. Griffith-Jones, "'The Sins of the Fathers' — Tort Liability for Pre-Natal Injuries", (1974) 90 Law Quarterly Rev. 513; J.G. Fleming *op. cit.*, note 23, at pp. 159-61, 644-5, & 668-9; W. Prosser, *op. cit.*, note 16, at pp. 335-8, 864, 883; J. Carbonnier, "Droit Civil", 9e éd. Paris; Presses Universitaires de France, 1971, Tomes I and II, at Tome I, pp. 179-84; G. Marty and P. Raynaud, "Droit Civil" 2e éd. Paris; Sirey, 1967, Vols. I and II, at Vol. II, p. 360.

The parent may also have a right of action, see for example: *O'Neill v. Morse* 385 Mich. 130; 188 N.W. 2d. 785 (1971); *Trib. gr. inst. Sein* 20 janv. 1962, J.C.P. 62éd. G. IV 68; *Langlois v. Meunier* [1973] C.S. 301 (Québec).

584. See references, *ibid.*, generally, and Law Commission (United Kingdom) Report, in particular, especially at p. 41.

585. See Editorial, "The Rights of the Mentally Handicapped", The Lancet 1973, 1(818), 1295, where a further distinction is suggested between the mentally ill and the mentally handicapped in that the latter can mature, develop and function as ordinary citizens if given the chance. There is also an argument for including those with temporarily reduced mental capacity, such as patients in extreme pain, within the class of the "temporarily factually, mentally incompetent" and according them the safeguards which this entails, as far as consent to medical interventions is concerned.

Also see G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 151, who divide mental incompetency into two classifications, mental illness and mental retardation, and say that one must distinguish numerous levels within each of these.

586. See *supra*, p. 83 *et seq.* and *infra*, pp. 100-101.

Also see Annas, Glantz and Katz, *ibid.*, at pp. 147-151.

587. R. Neville, *supra*, note 553, at p. 349.

588. *Ibid.*

589. See Fed. Reg. 23rd Aug. 1974, 30656 (Proposed Rules); 45 C.F.R. 46 § 46.504(c) which provides: "Institutionalized mentally disabled individuals may not be included in [research] — unless: — (c) The individual's assent to — participation [in research] has also been secured, when — he or she has sufficient mental capacity to understand what is proposed and to express an opinion as to his or her participation".

590. That institutionalization does not *necessarily* connote legal incompetence nor, of course, factual incompetence has been legislated in California: see *California Penal Code* (Supp. 1975) § 2672(b) (c).

Institutionalization may be voluntary or involuntary, but this does not automatically determine factual or legal competence to give "informed" consent, as the criterion for involuntary admission to a mental hospital may be dangerousness to oneself or others (see for example, *The Mental Health Act* R.S.O. 1970 c.269, section 8(1)(*a*)), which does not, of itself, connote factual incompetency. With respect to legal incompetence, it depends whether in the particular jurisdiction involuntary commitment carries a presumption of this. The Ontario legislation (*ibid.*), for example does not. *Section 32(3)* requires a medical examination after admission on the basis of which a certificate of incompetence *may* be issued.

591. Legal incompetency can arise in two ways which represent two factual realities, but both of which have the same legal implications. Firstly a person may be described as legally incompetent because he is factually incompetent and the effect of this is legal incompetence. Secondly a person may have been declared legally incompetent by a legal process of commitment or interdiction, in which case he is and remains legally incompetent, totally or partially depending on the effect of the legal process, until the order is lifted, even though he may have intervals of factual competence. In every case the circumstances relating to the factual competency of each individual person must be examined, in conjunction with the applicable laws of the jurisdiction relevant to mental incompetents in order to determine a particular person's legal competency, and thus one can assess the overall competency of that person to consent to a medical intervention or to medical research.

592. See P. Laget, *supra*, note 41, at p. 310; F. Heleine, *supra*, note 318, at p. 43; L. Kornprobst and S. Delphin, *op. cit.*, note 62, at Nos. 55, 60, 65; R. Boucher *et al, supra*, note 62, at p. 488; R. Piédelièvre et E. Fournier, *supra*, note 246, at Tome I, p. 103; X. Ryckmans and R. Meert-van de Put, *op. cit.*, note 62, at No. 595; A. Mayrand, *op. cit.*, note 43, at No. 41; P.-J. Doll, *supra*, note 36, at No. 5; R. Kierkens *op. cit.*, note 477, at No. 195; V.C. Heldman, *supra*, note 188, at pp. 163-170; M.F. Ratnoff, *supra*, note 63, at p. 495 *et seq*; J.A. Robertson, *supra*, note 532; R.G. Spece, *supra*, note 19; A.R. Holder, *op. cit.*, note 54, at p. 243.

"Notes 'Sale of Human Body Parts'", *supra*, note 315, at p. 1197; D.A. Frenkel, *supra*, note 247; *Kaimowitz v. Department of Mental Health for the State of Michigan*, cited *supra*, note 115.

593. See W.F. Cook, "Transplantation — Incompetent Donors: Was the first Step or the Last Taken in Strunk & Strunk? (Ky 445 S.W. 2d. 145)", (1970) 58 Calif. L. Rev. 754, where the author suggests a possible justification for using a criterion of social worth, that is the worth of the proposed incompetent organ donor in comparison with that of the competent recipient, is the result thereby attained of "social good by restoring a more productive citizen to gainful employment" (at p. 769).

Also see R.A. Koory, "Equity — Transplants — Power of Court to Authorize Removal of Kidney from Mental Incompetent for Transplantation into Brother", (1970) 16 Wayne L. Rev. 1460, at p. 1467, f.n. 62, where the point is considered whether an incompetent might provide a useful function supplying others with organs and thus "pay his own way through life".

594. See: Laget, Heleine, Kornprobst, Boucher, Piédelièvre, Ryckmans and Meert-van de Put, Mayrand, Doll, Dierkins, all as cited *supra*, note 592.

595. L. Kornprobst, *op. cit.*, note 12, at p. 243.

596. See Articles 290, 325, 343, 986 *Civil Code of the Province of Quebec*.

597. A. Mayrand, *op. cit.*, note 43, at No. 42; F. Heleine *supra*, note 318, at p. 43.

This interpretation is adopted on the basis that Article 20 expressly provides, under certain conditions, for experimentation on, or organ donation by, either a competent adult, or a discerning minor who may be legally incompetent, although he must be factually competent, and that the need for, and existence of, this express provision rebuts any implication that such interventions may be performed on persons not falling within one or other of these two categories, and any implication that "proxy" consent alone can be effective in any such situation.

598. See J.-L. Baudouin, *op. cit.*, note 339, at No. 192.

599. See Heldman, Ratnoff, Robertson, Spece, Holder, Michigan Law Rev., and Frenkel, all as cited *supra*, note 592.

600. See statutes cited *supra*, notes 463, 516, 517, 518.

601. Working Paper No. 5, *supra*, note 283, at No. 50, p. 28. "Report" *supra*, note 283, at p. 51, No. 113.

602. See *supra*, pp. 78-80.

603. See *supra*, note 532.

604. Cited *supra*, note 115.

605. See G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at pp. 175-178.

606. See, for example, *In re Moore* 221 S.E. 2d. 307 (N.C. 1976); *Cook v. Oregon* 9 Orc. App. 224, 495 P. 2d. 768 (1972); *In re Sallmaier* 378 N.Y.S. 2d. 989 (N.Y. Sup. Ct. Jan 26, 1976).

607. Fed. Reg. 23rd Aug. 1974, 30655; 45 C.F.R. § 46.504a.

Also see R.Q. Marston, "Medical Science The Clinical Trial and Society", The Hastings Center Report 3(2) 1 (1973) who believes the only type of research that should be allowed on the mentally ill is that related to mental disease.

608. *Supra*, note 65.

609. B. Mishkin, *supra*, note 557, at p. 282.

610. *Supra*, note 69, at I Basic Principles parag. II.

Note that the "Draft Code of Ethics on Human Experimentation (1961)" B.M.J. 1962, 2, 1119, which was the "avant-projet" of the Declaration of Helsinki, required the subject to "be in such a mental, physical and legal state as to be able to exercise fully his power of choice" (this is clearly taken from Article 1, Nuremberg Code, *supra*, note 65) and excluded experimentation on children, incompetents or "captive groups". This was altered, apparently largely due to American influence, to allow for "proxy" consent to be given for a "legally incompetent" person ("Declaration of Helsinki. Recommendations guiding medical doctors in biomedical research involving human subjects" Adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, at parag. III 3(a)) and for the use of prisoners as subjects (see M.J. Bloom, *supra*, note 63, at p. 1087). This original 1964 Declaration of Helsinki, however, retained a provision (III 3(b)), that "the subject of clinical research should be in such a mental, physical and legal state as to be able to exercise fully his power of choice".

It is interesting that the 1964 Declaration was amended, in Tokyo in 1975, *inter alia* by omitting the provision III 3(b). One can only speculate why this was done, but there was probably an implication from the cumulative effect of the two paragraphs referred to above, that factual competence was required, and perhaps freedom of movement, and "proxy" consent could only be given in a situation where legal, and not factual, incompetence was the sole defect. The 1975 Declaration provides for situations of "consent under duress", "legal incompetence" and "physical or mental capacity making it impossible to obtain informed consent", when "proxy" consent is acceptable. This may represent a major change as far as "special" subjects are concerned between the 1964 and 1975 versions of the Declaration of Helsinki.

Also see W.H.O. Principles for the Clinical Evaluation of Drugs *supra*, note 123, at § 4.1, p. 18, which allows for consent of the legal guardian in cases of "legal incapacity", seemingly to non-therapeutic research as the statement is made that "the subjects . . . may be healthy volunteers . . . whose consent has not been sought because . . . they were not competent to give it" (at p. 7). Because "legal incapacity" is specified, this may raise a presumption that such consent may not be given on behalf of a factually incompetent person, although the Declaration of Helsinki also speaks of "legal incompetence",

which presumably is a synonym for "legal incapacity" and makes clear this includes "physical or mental incapacity" (*ibid.*, 1975 version at I Basic Principles, parag. II).

611. *Supra*, note 67, at p. 2.

612. "The Report of the Committee to Investigate Medical Experiments on Staff Volunteers" *supra*, note 326, at § 3:2.

613. *Supra*, note 68.

Cf. New York State, *N.Y. Pub. Health Law* § 2440-2446 (Supp. 1976) which governs non-therapeutic human research and, at § 2442 under the title "Informed Consent" requires that no such research "may be conducted in this State in the absence of the voluntary informed consent subscribed to in writing by the human subject. . . . If the human subject be . . . legally unable to render consent, such consent shall be subscribed to in writing by such other person as may be legally empowered to act on behalf of the human subject". This provision is far from clear, as the title and first part imply that "informed" consent is essential and that therefore the second part of the provision should be interpreted as only making an exception to personal "informed" consent in the case of legal, but not factual, incapacity.

614. See *supra*, pp. 80-81.

615. D.A. Frenkel, *supra*, note 247, at p. 9.

616. See G.E.W. Wolstenholme, "An Old-Established Procedure: The Development of Blood Transfusion", in "Wolstenholme and O'Connor eds.", *op. cit.*, note 315, p. 24, at p. 26, who gives this historical example of research.

617. See G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, at p. 240.

618. See, for example, *Ruffin v. Commonwealth* 62 Va. [21 Gratt] 790 [1871] (Virginia), where the Court stated the prisoner "has, as a consequence of his crime, not only forfeited his liberty, but all his personal rights except those which the law in its humanity accords to him. He is for the time being the slave of the State"; P.-J. Doll, *supra*, note 508, at p. 822, who says that Article 36 du *Code pénal* (France) "dispose que l'individu condamné à une peine afflictive perpétuelle est déchu de tous ses droits civils" and all power, or right, to give consent therefore appears to be excluded.

619. For a discussion of prisoners' rights and legal capacity in general, see: G. Hawkins, "The Prison. Policy and Practice", Chicago and London. The University of Chicago Press, 1976.

And with particular reference to such rights in the medical relationship see: W.G. Todd, *supra*, note 80, at p. 800 *et seq.*; A.R. Holder, *op. cit.*, note 54, at pp. 13-15; L. Vandervort, "Legal Aspects of the Medical Treatment of Penitentiary Inmates", (1977) 3 Queen's Law J. 3:368.

620. B. Starkman, *supra*, note 18, at p. 23, with whom I agree, argues that procedural protections of institutionalized persons are not enough, rather the substantive law must articulate the civil rights of these persons in the context of practices involving the integrity of the individual.

621. See for example: W.G. Todd, *supra*, note 80, at p. 805; G. Hawkins, *supra*, note 619, at p. 136, who says that "until well into the 1960s . . . the prisoner

found that the law, to use Gerhard Mueller's phrase, 'left him at the prison entrance''.

622. A.B. Sabin, A.J. Bronstein, W.N. Hubbard, ''The Military/The Prisoner'', in ''Experiments and Research with Humans: Values in Conflict'', National Academy of Sciences, Academy Forum, Washington, 1975, (hereafter referred to as ''National Academy of Sciences Forum'') p. 127, per Bronstein, at pp. 130-5.

623. *Ibid.*, at p. 131.

624. See S. Spicker, ''Inquiry and Commentary'', part of the discussion led by A.B. Sabin *et al*, *ibid.*, at p. 145.

625. Lord Kilbrandon, ''Final Discussion'', in ''Wolstenholme and O'Connor eds.'', *op. cit.*, note 315, p. 202, at p. 205.

626. P. Ramsey, *supra*, note 201, at p. 705.

627. W.J. Estelle, ''The Changing Profile and Conditions Surrounding Clinical Research in Prisons'', Clin. Pharm. & Therap. 13(5) 831 (1972) (Emphasis added).

Note the use of the possessive pronoun when describing prisoners and also the way in which they are seen as commodities rather than persons.

628. J.D. Moore, ''The Deer Lodge Research Unit'', Clin. Pharm. & Therap. 13(5) 833 (1972), at p. 834.

629. R.W. Newman, ''The Participation of Prisoners in Clinical Research'', in ''Ladimer and Newman eds.'', *op. cit.*, note 10, at p. 467.

630. J.C. Wohlleb, ''Research on Prisoners'', N.E.J.M. 288(14) 742 (1973); F.G. McMahon, ''The 'Normal' Prisoner in Medical Research'', J. Clin. Pharm. 12(2) 71 (1972); R. Burt, ''Inquiry and Commentary'', in ''National Academy of Sciences Forum'', *supra*, note 622, at p. 144.

631. P.B. Meyer, ''Drug Experiments on Prisoners. Ethical Economic or Exploitative?'', Massachusetts; Lexington Books, 1976, at p. 35.

632. J.P. Tupin, *supra*, note 441, at p. 255; G. Bach — Y -- Rita, ''The Prisoner as an Experimental Subject'', J.A.M.A. 229(1) 45 (1974), notes that there is a problem of privacy when any information the prisoner discloses becomes the property of the state, especially when there is no guarantee the information will not be used against the prisoner.

633. W.B. Bean, in ''A Testament of Duty: Some Strictures on Moral Responsibility in Clinical Research'', Arch. Int. Med. 134 (5) 854, refers to condemned criminals being used for medical experiments in ancient Persia and Egypt, and during the Renaissance.

634. For example J. Paquin, *op. cit.*, note 170, at p. 359; R. Dierkens, *op. cit.*, note 477, at Nos. 198, 199.

635. Assuming this is possible, see *infra*, pp. 100-103.

636. A. Decocq, *op. cit.*, note 11, at No. 100, p. 79: G. Bourguignon, ''Les conditions morales de l'expérimentation sur l'homme sain ou malade'', in ''Premier congrès international de morale médicale. Communications'', Paris; Ordre National des Médecins, 1955, p. 67, at p. 68.

Also see: C. Bernard, "An Introduction to the Study of Experimental Medicine", translated by Henry Copley Green, New York; MacMillan Co., 1927, at p. 101; J. Fletcher, *supra*, note 62, at p. 636; M.H. Pappworth, *op. cit.*, note 308, at p. 194; P.B. Meyers, *op. cit.*, note 631, at pp. 65-66, 79-80; P.-J. Doll, *supra*, note 508, at p. 822; and B. Dickens, *supra*, note 316, at p. 22, who argue against allowing the use of prisoners as experimental subjects, which would apply *a fortiori* to the death penalty being carried out in this way.

637. M.B. Visscher, *op. cit.*, note 252, at p. 65.

638. P.B. Meyer, *op. cit.*, note 631, at p. 6.

639. Fed. Reg. 14th Jan 1977, 3082-3.

640. See R. Branson, "Prison Research: National Commission Says 'No, Unless . . .'", The Hastings Center Report 7(1) 15 (1977), citing M.E. Jaffe and C.S. Snoddy, "An International Survey of Clincal Research in Volunteers", Report prepared for the National Commission, Feb 10, 1976, p. 4.

641. B. Dickens, *supra*, note 316, at p. 22.

642. M.D. Eilenberg *et al*, *supra*, note 255.

Also see M.H. Pappworth, *op. cit.*, note 308, at p. 194, who says prisoners are not used as experimental subjects in Britain.

643. For example, see a paper prepared for the Law Reform Commission of Canada by G. Ferguson, "A Survey of the Literature on Psychiatric & Medical Techniques used in Canada for Personality Control", (unpublished) which shows that clearly experimental procedures, of doubtful therapeutic efficacy, are used in some Canadian prisons.

Also see N. Goodwin, "The Legal Aspects of Human Experimentation", Canadian Hospital 47(1) 33 (1970), at p. 35, who, as Director of Medical Services, *Department of Correctional Services*, Government of Ontario, advocated in an article in a medical journal, that *to avoid* litigation a researcher should: (a) conduct the experiment as part of treatment; (b) arrange for it to be prescribed by the personal physician from whom the subject (*Note* the description used is subject, not patient!) sought help; and (c) only if (a) and (b) were impossible was it necessary to obtain consent and explain the dangers involved, but to "promote the natural laws of research by means of human experimentation it is prudent to avoid the necessity for (c)". There is obviously deception of the subject advocated and intended here, but I query the extent to which deception of the wider community is also desired, and the extent to which such practices are used to mask experimental procedures carried out in prisons?

644. Cited *supra*, note 65.

645. Cited *supra*, note 69.

646. *Supra*, note 610.

647. For example Pennsylvania: *3 Pa. Bull* No 2667 (1973); A.J. Bronstein, *supra*, note 622, at p. 134, says Massachusetts and Illinois have also banned the use of prisoners.

Also see United States National Commission "Report", Fed. Reg. 14th Jan.1977, 3082, Chapter 4, parags. 4 & 5.

648. For example:

Okla. Stat. Ann. Tit. 63 (1973) § 47.1- § 47.5;

Iowa Code Ann. § 246.47 (1969);

Cal. Penal Code § 3049.5 (Supp. 1975).

Also see G.J. Annas, L.H. Glantz and B.F. Katz, *op. cit.*, note 63, pp. 128-132.

649. Fed. Reg. 14th Jan 1977, 3082, f.n. 2.

650. L'article D. 380 *Code de procédure pénale* (complet par le décret 12 septembre 1972).

651. Although the contrary was suggested, in essence, by N. Goodwin, *supra*, note 643.

652. F.J. Ayd, *supra*, note 301, at p. 772.

653. C.H. Fellner and J.R. Marshall, "Twelve Kidney Donors", JAMA 206(12) 2703 (1968).

654. D.C. Martin *et al*, *supra*, note 129, at p. 1427.

655. See *supra*, pp. 15-16.

656. See G. Bach-Y-Rita, *supra*, note 632, at p. 45, who describes the phenomenon of institutionalization in terms of a desire to acquiesce to the wishes of the keeper and an emotional transference to a parent-child relationship; B.S. Laves, "Legal Aspects of Experimentation with Institutionalized Mentally Disabled Subjects", J. Clin. Pharm. 16(10) Pt. 2.592 (1976), at p. 597.

657. F.J. Ayd, *supra*, note 301, at p. 776.

658. Loss of freedom of choice of his physician may have a coercive effect apart from that represented by loss of this liberty, itself. If the treating physician is seen by the prisoner as part of the prison institution, because the physician is chosen or employed by the prison, the prisoner may feel compelled to consent to recommended treatment, for fear of receiving a "bad mark", or an unfavourable medical report, which may count against him in such matters as parole decisions.

659. See Report & Recommendations United States National Commission, "Research Involving Prisoners", Fed. Reg. 14th Jan 1977, 3076-3091.

660. R. Curtis Morris, "Guidelines for accepting volunteers: Consent, ethical implications and the function of a peer review", Clin. Pharm. Therap. 13(5) 782 (1972), at p. 785.

661. D.C. Martin *et al*, *supra*, note 129, at p. 1428, Table 1.

662. P.B. Meyer, *op. cit.*, note 631, at p. 58.

663. See: D.C. Martin *et al*, *supra*, note 129, at p. 1427; P.B. Meyer, *ibid.*, pp. 10-15; L. Lasagna, "Special Subjects in Human Experimentation", in

"Freund ed.", *op. cit.*, note 6, p. 262, at pp. 264-5, who says prison volunteers become "the elite of their own society". Is this, in itself, a coercive element, especially when there is peer group pressure on individual members by this elite, to conform to the regime of the experiment? See F.J. Ayd *supra*, note 301, at p. 777.

664. See P. Freund, "Ethical Problems in Human Experimentation", N.E.J.M. 273(13) 687 (1965), at p. 691.

665. W.G. Todd, *supra*, note 80, at p. 811.

666. Fed. Reg. 14th Jan 1977, 3078.

667. *Ibid.*, 3080, Recommendation 3C, Comment (iii).

Note that the requirements recommended by the United States "National Commission" in this respect, are very specific and include seventeen separate headings such as single occupancy cells, private toilets, etc.

668. *Ibid.*, Comment (iv).

669. Fed. Reg. 14 Jan. 1977, 3079.

670. N. Hershey and R.D. Miller, *op. cit.*, note 63, at p. 65.

671. See for example: *Mackey v. Procunier* 477 F. 2d. 877 (9th Circ. 1973); *Knecht v. Gillman* 488 F. 2d. 1136 (8th Circ. 1973).

672. *Criminal Code* R.S.C. 1970 c-34, as amended by R.S.C. c.11 (1st Supp.); R.S.C. 1970 c.2 (2nd Supp); S.C. 1972 c.13; S.C. 1973-74 c.50.

Note that the Code abrogates all common law offences, section 8(a), but retains any "rule and principle of the common law that renders any circumstance a justification or excuse for an act or a defence to a charge", "except . . . as . . . altered by or inconsistent with this Act or any other Act of the Parliament of Canada", section 7(3).

Also note that under the *British North America Act* 1867 30-31 Victoria c. 3, section 92(15), the provinces have some incidental criminal jurisdiction. This is exercised, for example, in *The Human Tissue Gift Act* of Ontario (cited *supra*, note 283) section 13, which provides that a person knowingly contravening the Act is liable to a fine or imprisonment.

In fact this is the same situation, with respect to division of criminal jurisdiction, as pertains in the two other federal systems, the United States of America, and Australia, except that in these latter two general criminal jurisdiction is vested in the states and only criminal jurisdiction incidental to the specific heads of power of each of the federal governments, is vested in them.

673. United States Constitution Article I § 8.

The Constitution 63 and 64 Victoria, c. 12. *An Act to constitute the Commonwealth of Australia* section 51.

674. *Crimes Act* 1914 — 1973 (Cwth. Australia).

675. Note that even when the criminal law has been codified, the common law still plays a part, for example in interpretation of the elements of an offence.

For a comprehensive account of criminal law in Australia, see: C. Howard, "Australian Criminal Law", Sydney, Australia: The Law Book Co., 1970.

676. See W.R. LaFave and A.W. Scott, "Handbook on Criminal Law" St. Paul, Minn; West Publishing Co., 1972, at p. 3.

677. *Ibid.*, at p. 57.

678. See J.C. Smith and B. Hogan, "Criminal Law", 3rd ed., London; Butterworths, 1973.

679. For example, *Offences against the Person Act* 1861 24 and 25 Vict. c. 100.

680. P. Lombard *et al*, *op. cit.*, note 78, at pp. 126 and 132-3.

681. *Ibid.*

See also: J. Penneau, *op. cit.*, note 225, at No. 265.; G. Boyer Chammard and P. Monzein, *op. cit.*, note 56, at p. 71.

682. G. Boyer Chammard and P. Monzein, *ibid.*, at p. 73.

683. Cited *supra*, note 672.

684. I submit that the wording of section 198, "surgical or medical treatment . . . or any other lawful acts . . .", implies that such treatment is lawful. *Cf.* situation at Common Law, discussed *infra*, p. 106. (It is necessary, here to add a 'caveat'. Probably the more accepted interpretation of section 198 is that it does not affect the 'prima facie' legality or illegality of a medical intervention, rather it constitutes a *defence* to an act which would otherwise carry criminal liability, because the act in question falls within the parameters of an offence legislated in the *Criminal Code*. In my view the interpretation I have suggested is preferable, but this depends on the phrase "any other lawful acts" qualifying "surgical or medical treatment", which historically was probably not intended in drafting the legislation, as the former phrase was meant to cover acts, other than medical ones, which were dangerous but lawful. See H.E. Taschereau, "The Criminal Law Consolidation and Amendments Acts of 1869, 32-33 Vict. for the Dominion of Canada", Vol. I & II, Montreal; Lovell Printing and Publishing Co., 1874, at Vol. I, p. 204.)

685. Note that there is no requirement for consent of the patient, but, I suggest, this may be implied into the requirement of "reasonable care", in sections 45 and 198. There is, however, a historical difficulty with this interpretation, as shown by B. Starkman (*supra*), note 18, at pp. 5-6) who analyzes Stephen's Digest of Criminal Law, 1st and 4th eds. Macmillan & Co., London, 1877, 1887, on which these sections are based, and who concludes that *section 45* was only intended to cover emergency situations where the patient was incapable of consent.

686. See G. Dworkin, *supra*, note 524, at pp. 356-7.

687. For example, B. Starkman, *supra*, note 18, at p. 47, says as far as he was able to ascertain there has never been a criminal charge resulting from medical experimentation laid in Canada.

688. See for example, *Strunk v. Strunk*, cited *supra*, note 53, at pp. 147-8, where the Court requires "benefit of such persons as are incapable of protecting themselves" to authorize an organ donation operation, but makes no mention

of benefit when referring to the "common clinical practice" "of transferring tissue from one human being to another".

689. See P. Lombard *et al*, *op. cit.*, note 78, at p. 128; G. Boyer Chammard et P. Monzein, *op. cit.*, note 56, at p. 175.

690. G. Levasseur, *supra*, note 402, at p. 140. (Emphasis added)

691. *Ibid.*, p. 139.

692. Article 327 *Code pénal* (France).

693. See for example, *Offences against the Person Act* 1861 (United Kingdom), cited *supra*, note 679, section 20.

694. For example *Criminal Code* (Canada) cited *supra*, note 672, section 244.

695. See for example: *Mathew v. Ollerton* 90 Eng. Rep. 438; Comberback 218 (1693), where the court held a licence by a person to beat him was void as being *against the peace*.

696. It is possible that the practice (or rather malpractice) of medicine could pose threats to the community. See, for example, G. Levasseur, *supra*, note 402, at p. 138: "Le bien des citoyens conditionnant le bien de l'État, les pouvoirs publics se doivent d'accorder au bon exercice de la profession médicale: facilités, encouragements, récompenses, garanties de qualité et succès. Il leur appartient d'assurer pas des mesures appropriées . . . la sauvegarde de la santé publique, qui doit être un de leurs soucis majeurs."

More generally see: *Spead v. Tomlinson* 73 N.H. 46, 59A. 376 (1904), which held the state has a right and duty to secure the well-being of all and, to this end, can impose duties which are then owed to the state and not to the individual for whose benefit they are imposed. This approach shows why the consent of the individual is not a defence to a criminal charge as the individual does not have the power to waive the duty owed to the state; J. Penneau, *op. cit.*, note 225, at No. 327, who says juridical liability expresses society's reprobation of the transgression of one of its rules, which are necessary to the *moral equilibrium* of the *group*.

697. See G. Dworkin, *supra*, note 524, at p. 355, who discusses the old Common Law crime of mayhem (maim), which was committed when a person so injured another as to make him less able to fight, or to defend himself, or to annoy an adversary. The act was illegal because it *deprived the king of a fighting man* — that is on the basis of community interest or public policy.

698. See for example *Bravery v. Bravery* [1954] 3 All E.R. 59, where Lord Justice Denning held that a sterilization operation on a man was unlawful even though he consented, there being "no just cause or excuse" for it and that it was "plainly injurious to the public interest". The "mores" that this judgment reflects may have changed in England. Also note that the characterization of unlawfulness is based on injury to the society, and that the procedure is then not justified by consent of the patient, but rather by the procedure being undertaken "for the sake of a man's health". Assuming that there are justifications other than therapy for some medical interventions, (for example benefit to the community) this raises the issue of the lawfulness of non-therapeutic human experimentation in the form of the question: does the good to society ever justify the injury to the public interest perpetrated by using humans as experimental subjects, and if so, when? That is, consent is

necessary to but not determinative of, the lawfulness of such an intervention, as it is the public interest which is being protected by the criminal law in protecting the individual.

699. See for example: F.H. Beale, *supra*, note 272: "Notes 'Sale of Human Body Parts'", *supra*, note 274, at p. 1238.

For an excellent recent discussion of this matter see: A. Rubenstein, "The Victim's Consent in Criminal Law: An Essay on the Extent of the Decriminalizing Element of the Crime Concept", in E.M. Wise and G.O.W. Mueller, eds., "Studies in Comparative Criminal Law", Illinois; Charles C. Thomas, 1975, at pp. 189-210; G. Levasseur, *supra*, note 402, at pp. 140-1, who says a person cannot confer on another the right to attack his physical integrity. That is consent is necessary, except in special circumstances, but it is not a sufficient justification in French Law for an act constituting civil or penal fault — in other words it is not solely determinative of legality.

700. See for example, *Criminal Code* (Canada), cited *supra*, note 672, section 14.

701. W. Blackstone, "Commentaries", *op. cit.*, note 491, at 4:205-8; H. Roxburgh, "Experiments on Human Subjects", (1963) 3 Medicine Science and the Law, 132, at pp. 135-6.

702. The word "self-inflicted" should, I suggest, be read in the sense of meaning the injury was willingly sustained, rather than meaning the act of infliction was carried out by the person themselves.

703. A. Rubenstein, *supra*, note 699, at p. 200.

704. *R v. Clarence* (1888) 22 Q. B.D. 23: *Papadimotropoulous v. R* (1957) 98 C.L.R. 249.

See: B. Dickens, *supra*, note 62, at pp. 395-6, who discusses the effect of mistake on consent, when the latter is relevant for criminal law purposes. Simply stated, mistake will not vitiate the consent, unless it is as to the nature of the act and not just its consequences.

705. B. Starkman, *supra*, note 18, at p. 43.

Note that Article 204 of Stephen's Digest, *supra*, note 685, provides that: "Everyone has a right to consent to the infliction of any bodily injury in the nature of a surgical operation upon himself or upon any child under his care, and *too young to exercise* a *reasonable discretion* in such a matter . . . " Stephen appended a footnote that he "knew of no authority for these propositions, but . . . they require none". The former statement recognizes the capacity of a child capable of discretion to consent for himself and implies that he must do so for criminal law purposes.

It was a defence at common law if a minor of the age of discretion consented to a criminal offence that required the absence of consent to constitute the offence. See Starkman, *ibid*.

706. See for example: *Criminal Code* (Canada) *supra*, note 672, sections 21, 22, 421, 422, 423; C. Howard, *supra*, note 675, at pp. 250-86.

These criminal offences arising from ancillary responsibility would apply generally to any medical situation recognized as involving criminal activity, not just to those where the involvement arose from giving "proxy" consent.

707. For example *Cal. Penal Code* § 273(a) West 1970, which provides it is a misdemeanor to endanger a minor's health or subject him to unjustifiable physical or mental suffering.

708. See, for example, *An Act respecting the protection of children subject to ill-treatment, supra*, note 566.