CONSENT IN THERAPY AND EXPERIMENTATION

Thesis submitted for the degree of Master of Laws (L.L.M)

by

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To the memory of my father,

Mohammed
(1929-1984)

To my mother.

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TABLE OF CONTENTS

Summary.

During the last few decades, it has become recognised that patients can legitimately exercise their right to autonomy and self-determination in health care. Among the obvious privileges that the application of this principle accords to the patient in the medical context is taking part in the decision-making process and an obligation on the part of health professional to respect his or her choices with respect to his or her decisions in health care. Hence, among other things, the right to consent to or refuse treatment and the right to die, became natural and rational claims for patients.

In the present thesis the writer is concerned with the patient's right to consent to both therapy and experimentation and the law's role in enforcing this right. This discussion commences by outlining the ethical principles that should be observed in the doctor/patient relationship. The writer is mainly concerned here with the analysis of the principle of autonomy and respect.

Following this introductory chapter, and before looking at the the nature of consent in the medical context, its forms and elements, and the value and role of the consent document, it will be convenient to examine the patient's right to consent to or refuse medical intervention.

Since the docrine of informed consent which is tied up with the principle of autonomy and self-determination first appeared in the U.S.A, an analysis of the development of this doctrine is in order in chapter three. This historical analysis is relevant to the following discussion of the status of consent under the British legal system which is outlined in chapter four.

The second part of the thesis looks at consent and its implications in relation to human experimentation. Before considering the law governing the issue, it will be convenient to start this discussion with a general consideration of the ethics of human experimentation. Here one is concerned with the value society attaches to human research and its moral justification, if there is any, and the ethical and practical problems raised by consent. The main question which is asked in this respect is whether it is possible for the human subject to be fully informed about the potential risks of the procedures, bearing in mind that even the investigator himself or herself might be unaware of certain of these risks. In other words, is it possible to render a valid and informed consent in this area of medicine?. Also relevant to the present discussion is the question of whether there is a need to control the conduct of experiments and how such a control can be achieved.

The last chapter concentrates on the development of the law of consent in the experimental setting. The analysis of this issue will be made on the light of internationl agreements about the use of human subjects in medical research namely the Nuremberg code and the Declaration of Helsinki.

ABBREVIATIONS

Ari. L. Rev.....	Arizona Law Review.
B. M. J.....	British Medical Journal.
Cali. L. Rev.....	California Law Review.
Cancer. Treat. Rep...	Cancer Treatment Report.
Clin.Phar. Ther.....	Clinical Pharmacology and Therapeutics.
Crim. L. Rev.....	Criminal Law Review.
Duq. Univ. L. Rev.....	Duquesne University Law Review.
Int. J. L. Psychiatry..	International Jour. of Law & Psychiatry.
J. Crim. L. Crim.....	Journal of Criminal Law and Criminology.
J. A. M. A.....	Journal of American Medical Association
Jour. H. P. P. L.....	Journal of Health, Politics, Policy and Law.
Jour. Med. Phil.....	Journal of Medicine and Philosophy.
Jour. Med. Ethics.....	Journal of Medical Ethics.
Kans. L. Rev	Kansas Law Review.
L. Q. R.....	Law Quarterly Review.
Leg. Med. Q.....	Legal Medical Quarterly.
M. L. R.....	Modern Law Review.
Med. Leg. Jour.....	Medico-Legal Journal.
Med. Sci. Law.....	Medicine, Science & the Law.
Minn. L. Rev.....	Minnesota Law Review.
N. E. J. M.....	New England Journal of Medicine
N. L. J.....	New Law Journal
N.Y. Uni. L. .Rev.....	New York University Law Review.
Neb. L. Rev.....	Nebraska Law Review.
Proc. Roy. Soc. Med....	Proceedings Royal Society of Medicine.
S. L .T.....	Scots Law Times.
Sco. L. A. G.....	Scottish Legal Action Group.
Scott. Med. Jour.....	Scottish Medical Journal.
Soc. Sci .Med.....	Society Science and Medicine.
Texa. Rep. Biol. Med..	Texas Reports on Biology and Medicine.
Uni. Colo. L. Rev.....	University of Colorado Law Review.
Univ. Pitts. L. R.....	University of Pittsburgh Law Review.
Wis. L. Rev.....	Wisconsin Law Review.
Y.U.J.....	Yale University Journal.

CHAPTER ONE

INTRODUCTION

It is recognized that persons have a right to individual self-determination. There are many grounds on which this right has been asserted. These are political, philosophical, religious, moral and legal. The right also relies on the notion that human beings are capable of determining their own course of action in accordance with a plan they themselves have chosen.

In a similar way, patients have been accorded the same right during the last few decades. However, the call for patients' rights to self-determination has engendered a bitter controversy which is not surprising if one appreciates that patient self-determination is an idea alien to medicine. As Katz pointed out,

> "Since physicians have generally maintained that patients do not have the capacity to participate in decision-making, patient autonomy was not a concept inscribed in medicine's vocabulary."[1]

What is meant then by the term "Autonomy and self-determination"?. The starting point of the present discussion will be concerned with the notion of autonomy. Moreover, the need to make a full analysis of the principle of autonomy and other principles means that most of this chapter will be taken up with a rather abstract philosophical discussion in preparation for a more detailed exploration of the practical problems of consent to both therapy and experimentation.

1.1 NOTION OF AUTONOMY:

Tom Beauchamp and James Childress[2]define autonomy as a form of personal liberty of action where the individual determines his or her own course of action in accordance with a plan chosen by himself or herself. The autonomous person is one "who deliberates about and chooses plans and is capable of acting on the basis of such deliberations, just as a truly independent government is capable of controlling its territories and policies".[3]

A person of diminished autonomy, however, is to a considerable extent dependent on others and in some aspects does not have the capacity of deliberating or acting on the basis of such deliberations. Beauchamp and Childress come to the conclusion that the term autonomy as applied to individuals can be used quite broadly. It can refer to the person, the will, or action in society, and both internal and external constraints can limit autonomy.[4]

For Downie and Calman[5], to be autonomous is to have the ability to choose for oneself or more extensively to be able to formulate and carry out one's own plans and policies. The moral importance society attaches to these abilities, they argue, is reflected in its approval of traits of character such as being able to live on one's own initiative, having desires and plans in one's own life and the ability to decide for oneself without the help of others.

Conversely, to weaken an individual's capacity to deliberate about and carry out aims and policies of his or her own choosing is to that extent to hurt him or her as a person.

Kant mentioned another feature of the autonomous person; the ability to govern one's conduct by rules and values valid for others as well as oneself; "act only on that maxim through which you can at

the same time will that it should become a universal law."[6] That is, to be autonomous is to govern oneself, including making one's own choices in accordance with universalizable moral principles, i.e., principles that can be willed to be universally valid for everyone.

In analysing autonomy, Kant contrasted it with heteronomy (rule by other persons or conditions). To be heteronomous, is to lack the internal control of one's own life. Under heteronomy, Kant mentions both external and internal determinations of the will but not moral principles. One, he points out, is obliged to act in accordance with a moral rule, whereas one is only complying with a self legislated rule. Moreover, Kant also includes actions from fear and impulse as well as coerced actions under heteronomy.

Mill by contrast, was concerned about autonomy or as he called it,'the individuality of action and thought'. He points out that the state's interference with individual actions is legitimate only when it is necessary to prevent harm to other individuals. In this respect he wrote;

> "As soon as any part of a person's conduct affects prejudically the interest of others, society has jurisdiction over it....but there is no reason to entertaining any such question when a person's conduct affects no persons besides himself, or need not affect them unless they like (all the persons concerned being of full age and the ordinary amount of understanding). In all such cases, there should be perfect freedom, legal and social to do the action and stand the consequences."[7]

Mill recognizes the importance of a true character. He notes that a person with a true character is one of genuine individuality. Conversely, a person without character always depends on an authoritative environment and most notably, parents or family.[8] Mill

mentions 'firmness', 'self-control' and 'choosing a plan of life' as indispensible elements to a proper framing of one's character.

From this analysis, one can draw a comparison between the Kantian and Millian approaches to the concept of autonomy. It seems apparently that Mill and Kant had somewhat different objectives in treating the issue. Kant was concerned about moral autonomy, i,e the idea of giving oneself the moral law, or self-determination in accordance with morally valid principles. He argued that one has a moral duty to act in accordance with such principles. Mill, by contrast, was more interested in the concept of individual autonomy or self-determination. He believed that the individual's right to this form of self-determination or individuality is fundamental from the moral point of view. These two thoughts are different since Kant considered a "purely individual action as outside the moral order".[9]

There is, however, a consensus that a person is autonomous, if and only if he or she is self- governing. Autonomy as governance lies in the ability to legislate norms of conduct for oneself (Kant), and the ability to chart one's own course of action voluntarily (Mill).

It should be noted that there is a different between being autonomous and behaving autonomously, and being respected as an autonomous person.

1 : 2 RESPECT FOR AUTONOMY:

As Beauchamp and Childress put it, to respect autonomous individuals is "to recognize their right to self-governance by affirming that they are entitled to such autonomous determination free from imposed limitations".[10]

This principle has its origin in both Kant's and Mill's thoughts. For Kant, to respect an autonomous human being, or as he prefers to

say it, 'to respect a person as an end', is to take into consideration in one's conduct that he or she is self-determining and self-governing, or that he or she has desires, feelings and reasons.[11] He argues that the respect due to autonomous persons flows from the recognition that all persons "have unconditional worth solely as ends in themselves determining their destinies".[12]

To disregard a person's autonomy is to consider that person merely as a means for one's own ends, for he or she is made to behave in accordance with rules not of his or her choosing. Again, to show no consideration of a person's own judgements and decisions or to prevent him or her from acting on the basis of those considered decisions is to that extent to impair his or her autonomous personhood. For instance, if the physician does not mention any of the risks inherent in the proposed treatment and the patient consents to the operation being performed, the patient can not make a rational decision since he or she has not been provided with the necessary information to reach such a decision. By so doing the surgeon limits the patient's autonomy. In this respect Kant thinks that a moral relationship between autonomous persons requires a mutual respect for autonomy, and this raises interesting questions about whether a physician can have such a moral relationship if he or she withholds information.[13]

For Mill the autonomous person is free to act in whatever way he or she wishes as long as his or her actions do not go against the autonomous actions of others. That is to say persons' views and actions must be respected so long as they cause no serious harms to others. As has been said:

> "the principle of autonomy, like all moral principles, has only prima facie standing, it asserts a right of non-interference and correlatively an obligation not to constrain autonomous actions-nothing more but also

nothing less".[14]

Like most principles, the principle of respect for autonomy has an exception. It does not apply to persons who are unlikely to act in a sufficiently autonomous manner due to their immaturity, ignorance or coercion. Their actions and behaviour may be validly interfered with in order to prevent the harms they might suffer from such actions. In other words the intervention is for the sake of their welfare.[15] Even those who defend autonomy are in favour of the latter form of intervention, for they consider such actions either wholly or substantially non-autonomous. Further discussion of this point is in order later in this chapter.

(A) OTHER PRINCIPLES

There exist other principles included under the principle of respect for autonomy. In other words, to show respect for the autonomy of others is to employ the following moral principles when dealing with autonomous agents; these are the principles of non-maleficence, benevolence or compassion, justice or fairness and utility.

(1)-The Principle of Nonmaleficence:

In the health care context, the Hippocratic Oath mentions the principle of non-maleficence as well as the principle of benificence."I will apply dietetic measures for the benefit of the sick according to my ability and judgment, I will keep them from harm and injustice".[16]

The establishment of such a moral principle is due to certain obvious facts about human beings and their characteristics. One of

these characteristics is "human vulnerability". Human beings have bodies that can easily be injured by any attack.[17] This was one of the reasons which led all moralities to restrict the use of physical violence in social life. It also the reason which gave rise to the existence of the concept of assault. As Downie and Calman noted:

> "A concept like assault logically could not exist unless the human body were liable to physical damage , and in more general terms, principles such as 'one ought not harm' or 'one ought to help people in distress' clearly reflect the fact that people are liable to injury and vulnerable physically and psychologically to deliberate attacks or accidental mishaps."[18]

As the range of harms that can be inflicted on others is quite wide, the principle of nonmaleficence is likely to have several specific moral rules. In this respect, Gert[19] pointed out that the rules which prohibit harmful actions form the core of morality and he quoted the following:'Don't kill', 'Don't cause pain', 'Don't disable', 'Don't deprive of freedom or opportunity' and 'Don't deprive of pleasure'.[20] Of course none of these derivative rules is absolute and the same is true of the principle of nonmaleficence itself. For example it is a common procedure with the patient's consent-to inflict harm in order to prevent worse harms, e.g., to amputate an affected limb in order to prevent death.[21]

The duty of nonmaleficence requires the agents not only to refrain from inflicting actual harms, but also to refrain from exposing others to risks of harms.[22] There are many instances in which people do not expose themselves to risks but also impose them, deliberately, on others. A good illustration of risk taking and risk imposition is driving a vehicle with an excessive speed.

As the imposition of risks of harm on others is very common, there is no need for an explicit justification. Nevertheless in these cases law and morality recognize a standard of due care. This standard requires that the goals which are sought must be weighty and important enough to justify the risks imposed on others[23]. For example, rescuing people after an accident may justify the dangers created by speeding emergency vehicles.

The duty of nonmaleficence also requires agents to act carefully, because they may violate the duty in question unintentionally. The violation may be present in acts of commission as well as in acts of omission. To act thoughtfully and carefully is part of the other moral rules and principles such as the principle of nonmaleficence. As D'arcy[24] points out; "Negligence is not a separate moral species..., rather it applies to certain type of failure to meet obligations connected with many different species."[25] It includes "the failure to guard against risks of harm to other".[26] Negligence is "conduct which involves an unreasonably great risk of causing damage" or "conduct which falls below the standard established by law for the protection of others against unreasonably great risk of harm."[27] In the health care context, legal and moral standards require from the caring workers knowledge, skills and diligence. If the physician's conduct is judged to be below these standards, he or she acts negligently.

(2)-<u>The Principle of Benevolence</u>:

In addition to the duty of nonmaleficence considered so far, there exists another moral duty which requires not only refraining from harming people but also contributing to their welfare by the offering of positive help and assistance. Such beneficial actions constitute

the principle of benevolence or beneficence. It goes without saying that the principle of beneficence controls all those involved in the caring professions, but in this context some scholars[28]think that it is more appropriate to describe it by the term compassion.

Every human being has "the capacity to feel with others, to enter to some extent into their predicament and share their emotions."[29] The ability to understand other's feelings is part of compassion. Compassion, however, is not limited to the capacity to feel with others, i,e, it is not just passive. It requires the agent to act on the basis of the promptings of natural emotion. The caring professions in particular are required to develop in themselves the capacity to feel with others, including the capacity of being compassionate which demands an active response. Compassion, from another point of view, must be distinguished from, 'sympathy' and 'pity'.

Sympathy is used to describe someone with the capacity to share one's feelings or the possibility to act according to one's predicament. Compassion, by contrast, requires both responses. Pity is similar to sympathy in its passive mode but pity "can involve a certain condescension to its objects".[30]

It is important, however, to bear in mind that those who need compassion in health care are typically autonomous persons who temporarily loose their state of health. Under such circumstances, pity is not the suitable or the appropriate term to characterise the mode of dealing with such autonomous persons. The term compassion, however, does fit its objects; it implies positive help and assistance and imaginative understanding along with an awareness and consciousness of its objects.

(3)-The Principle of Justice or Fairness:

Some moral philosophers[31] considered fairness as the best explanation to justice. Desert (giving to each his or her right), however, is seen to be the most closely linked concept to justice in it broadest sense. That is, as has been said, "one acts justly toward a person when that person has been given what is due or owed, and thus, what he or she deserves and can legitimately claim"[32]. For instance, if a person has the required mark to graduate, justice requires that this person be awarded his or her degree. Beauchamp and Childress[33] argue that in order that persons deserve and can legitimately claim something, they must possess certain morally relevant properties such as being productive, or being in need. Similarly, the argument goes, it is unjust to burden or to reward someone who does not possess either of these moral properties. For example, it is wrong as a matter of justice to reward the chief for the work of his or her employees when the former did not contribute to the rewardable work. Looked at from this angle, justice is concerned with treating individuals rightly in the light of their own wants, needs and merits.

The principle of justice has another side which applies to one's dealing with one person or group as compared with others. This is sometimes called "distributive justice", and is usually described in the form 'like cases should be treated alike'. It does not mean, however, that it always wrong to discriminate for the advantage or against other people or groups, but rather that any such distinction or discrimination must have a justification. The presumption is that like cases must be treated alike, and the burden of justification is on the discriminator. For example, if two patients need renal dialysis, the presumption is that they should be treated alike, but

perhaps one has more utility to the community as a whole, or he or she has been promised treatment, and can therefore justifiably be preferred to the other if the resource is scarce. For the existance of such a promise gives him or her a moral right to receive the treatment before others.[34] But whether in the form of just "desert" or "just distribution", the concept of justice is connected with autonomous persons and the respect due to autonomy is due or deserved by each individual autonomous person alike.

(4)-The Principle of Utility:

The last principle involved in respect is that of utility. Utility is commonly explained as usefulness. The principle demands that in all circumstances, people ought to seek the best possible consequences or "the greatest possible balance of value over disvalue for all persons affected"[35] - or the least possible balance of disvalue in cases where only bad consequences are likely to result. For example, in the health care context whenever there is a choice between different but equally efficacious ways of treatment, the patient's benefits should be maximized, and the costs and risks minimized. If any other approach is followed, it would be considered as an unethical practice.

The Utilitarian method of taking decisions is done on the basis of balancing resources and comparing the actual needs of all persons affected. Accordingly, the right decision to take will be the one which is likely to promote the greatest amount of goodness for the greatest number of people.[36] This means that utility is not concerned with individuals but rather with majorities and aggregates. As Downie and Calman pointed out[37], utility might be considered as a principle for administrators and legislators. In fact it was adopted

in the nineteenth century as "a theory highlighting the need for the reform of the criminal code"[38]. Later, the theory developed to a new version - rule utilitarianism as opposed to act utilitarianism - in which the emphasis shifted from individual actions to the utility of policies, classes of actions and rules of behaviour. This led some scholars[39] to consider the principle of utility as an administrative expression of respect.

It is worth noting, however, that it is difficult to reconcile the idea of justice which requires that similar cases be treated alike with that of utility which suggests that some groups or even individuals may be treated better than others for the sought good of the aggregates.

1 : 3 SPECIAL GROUPS:

When considering the autonomous person and the attitude which is morally owed to autonomous persons it has been assumed that one is dealing with mature and rational adults. But sometimes this is not the case, since it is possible that the patient is a baby, perhaps even an embryo, a dementing elderly person, a mentally handicapped adult or someone in a coma. It is obvious that these persons are not in a position to act in a sufficiently autonomous manner. In fact, among individuals forming this group, there are some who have no autonomy at all, e.g., the embryo, the baby and the comatose patient or the patient with brain damage being kept on a ventilator. Others, however, have considerably impaired or otherwise inadequate autonomy, because they are young and immature or severely mentally handicapped. But does that mean that they are not due the respect accorded to autonomous persons?.

It should be noted that these cases are different from the standard case of the rational autonomous adult person in many aspects, and their discussion raises different questions. The case of the embryo and the comatose patient, for example, does not inquire whether they should be treated as autonomous agents, but rather when and which kind of respect, if there is any, must be shown to them during the processes of development into a person (embryo) and degeneration out of a person (comatose patient whose brain is decaying). In the case of persons with impaired or inadequate autonomy, however, the question is concerned with the amount of autonomy the person needs in order to be respected as a fully autonomous person. Therefore, in discussing these cases, it is necessary to group them in two distinctive groups;

(1)the first group includes the embryo and the patient with irreversible brain damage who is being kept breathing on a ventilator. The main questions which are raised in discussing these situations are when does life begin and when does it cease?. The answer to thess questions is of major importance since, it is believed, it determines the period during which respect for human life ought to be shown.

(2)the second group contains people suffering from mental handicap, mental disturbance and young children. The question here explores the extent to which paternalism is justifiable.

(A) Embryos and Comatose Patients:

It goes without saying that the central moral principle is that of respect for the autonomous agent. But for many philosophers, the main moral question remains "when does life begin"?, for many believe that the answer to this controversial question determines the time or the moment from which respect ought to be shown.

For the lay person, the moment of conception is the obvious answer

to the question of when life begins. It is known that conception is the identifiable event from which point the egg starts a continuous process that leads to maturity. From this view many people draw the implications that abortion is always wrong and that experiments on embryos at any stage of their development are wrong as well, for these experiments are seen to be performed on what is at least potentially a human being.[40]

Biologically, one may argue that life does not begin at conception. In a biological sense, life "is a constantly evolving process and conception is only one stage in such a process".[41] For instance, the egg is alive before conception and it undergoes a process of development without which conception is unlikely to materialize. The sperm too is also alive and wriggling.

Furthermore, at conception anything can begin, but not always life. Fertilisation can lead not to an embryo but to a tumor which can be fatal to the mother's life. No one presumably will invest this tumor with the rights and protections that many think are caused to exist at fertilisation. Another complication may be brought about if the fertilised egg splits to form twins. In this case the fertilised egg can not be considered a new individual.[42]

One can conclude that life is "a continuum and the emergence of the individual occurs gradually."[43] This conclusion has led some to argue that if life does not begin at conception and if one cannot claim that a new human being begins there, at least the potential for a new human being is then present, complete with its full genetic make-up and with all its uniqueness and individuality. Consequently, the fertilised egg which is the potential human being can be vested with some of the rights of the adult human being including the right to be allowed to to develop that potentiality. This is what is called

the potentiality argument.

The first point to note against the potentiality argument is that the fact that something will supposedly become, for example, X (even if it will inevitably become X, which is far from being the case with the fertilised egg and the adult human being) is not a convincing enough reason for treating it at the present time as if it were in fact X. Downie and Calman[44]use the illustration that an acorn is potentially an oak, but this does not render it obligatory on anybody, whoever it is, to allow or assist it to develop to an oak.

The second point is that, if one asserts that the fertilized egg is potentially a human being, it necessarily follows that the unfertilized egg is potentially a fertilized one. A fertilized egg is potentially a new human being on the condition that certain events happen to it like implantation, and certain events do not, like a spontaneous abortion. In a similar way, the unfertilized egg is unlikely to become a fertilized one unless certain events happen to it, like meeting a sperm and thereafter other events do not take place, like meeting a contraceptive. Therefore the fact that a fertilized egg is potentially an adult human being is not sufficient reason to invest the egg with the rights of the rational adult. It does not follow, however, that the egg as human genetic material has no moral significance. The appropriate question will then concern the amount of moral significance the egg possesses.

It is assumed that there is a continuance in the development before and after conception and that the moral consideration of the embryo will increase and grow in parallel with its stages of development. For the fertilized egg has some moral significance, but not a considerable one. In recognizing this fact, the Committee of Inquiry Into Human Fertilisation and Embryology[45], limited the

period in which experiments could be carried out and determined the bodies that are allowed to undertake such experiments.

An embryo with a developed brain and a central nervous system is morally much more significant. At this stage it is possible for the embryo to experience pain and perhaps some elementary sensory cognition. Accordingly, it will be a much more serious offence to kill an embryo at this stage than to kill it at an earlier stage. Another important stage in the acquisition of moral rights is the stage of the possibility of independent existence (viability) followed by the birth stage. Later comes childhood with its possibilities of having independent plans and purposes, then self-consciousness and at last the adult human being.[46]

It is worth noting here that the account given of the status of the embryo has important implications for abortion policy. As far as morality is concerned, abortion can not be easily defended around eight weeks, for it is around this age that the brain develops. However, it does not necessarily follow from this fact that abortion would be always wrong at this stage. The point is that the mother's wishes are not the only consideration. In other words there could be other factors affecting the health of the mother or social situations which have to be be weighed against the right of the embryo whose brain has developed.[47]

To summarise the point one would say that at conception there is no sign of a person or of a potential person, rather the embryo develops gradually into a person. But it should not be understood from that that there is no respect for non-persons. As has been said;

> " A being should be respected for the sort of being it is: living human tissue, an embryo with a brain and central nervous system, an embryo capable of independent existence, a child with plans of its own

and self-consciousness and finally a full autonomous adult."[48]

The second situation in this group concerns the comatose patient or the patient with brain damage being kept on a ventilator. The main question which is often asked in these situations is "when does death occur?", or what is the criterion for determining the occurrence of death and the test that might show that the criterion has been met.

Until recently, determining the death of a person caused no practical difficulties. Physicians used the traditional methods in establishing death, i.e., the cessation of breathing and the cessation of heart beat.

Advances in medicine and medical technology, however, gradually showed that this was not the the appropriate criterion for all purposes. Elective cardiac arrest, for instance, is necessary in open heart surgery. In addition there are many cases of spontaneous cardiac arrest which are followed by successful resuscitation. The use of mechanical ventilators brought major developments in techniques of resuscitation and life support for ill patients. The use of these techniques can have a very satisfactory outcome, but in some instances this is not the case, for example, where the patient's heart keeps beating on the machine for a considerable time after he or she stops breathing spontaneously, but his or her brain is irreversibly damaged.

In these circumstances many believe that maintaining the patient in costly intensive care is useless. Moreover, this may deny access to equipment to other patients who can better benefit from them. The development which had taken place in transplantation programmes also stressed the need to find out a more precise criterion for establishing death. Since most organs and other tissues must be taken from either a living, or a very recently dead, body, the determination

of the approximate moment of death is of special significance.

The question of what is death has two main types of answer. In the first one, death is taken as a moral question.[49] The appropriate time to treat someone as dead is when his or her moral standing "changes so radically that the same rights claims attributed to living persons are no longer attributed".[50] This approach suggests that an individual can be pronounced dead when he or she loses his or her personality, and consequently no respect ought to be shown to him or her as a human being. The second sort of answer looks at death from the biological perspective.[51] In order not to exclude any biologically living person whose moral standing has changed because of, e.g., a mental disease or senility, it is more appropriate to adopt an account which concentrates on biology rather on the personality.

There is a wide agreement that death can be defined as "the permanent cessation of the functioning of the organism as a whole."[52] The widely accepted criterion for the cessation of the functioning of the organism as a whole is irreversible brain damage or brain death.[53] This was a new criterion of death suggested in 1968 in an influential report of an *ad hoc* committee of the Harvard Medical School. This criterion is totally related to the permanent cessation of the functioning of the organism as a whole, for the brain is a fundamental necessity for the functioning of the organism as a whole. The brain "integrates, generates, and controls complex bodily activities."[54] The brain, for instance, controls the breathing mechanism through brain stem ventilatory centres and aids in the control of circulation through brain stem pressure control centres. If the brain is damaged, from, perhaps, a head injury or a spontaneous intercranial haemorrhage, this will cause an **apneoa** (inability to

breath) which is followed by a **vasodilatation** (opening of the peripheral blood vessels). As a result, heart failure occurs within a week. However if the patient is maintained by artificial ventilation, the heart will keep beating for some days and this will permit the function in other organs, e.g., kidneys, to be maintained. In such situations, the physician could declare as dead a comatose patient with no discernible central nervous system activity. This is followed by turning off the ventilator.[55]

Different sets of tests are used to diagnose death. For a normal death, i,e not complicated by artificial ventilation, the traditional tests of death-cessation of heart beat and ventilation-are still applicable.

The cessation of heart beat and circulation determine that the criteria of death have been met, since they are always followed by a permanent loss of the functioning of the whole brain. These tests, however, are useless when artificial ventilation is being used, for the functioning of the whole organism may cease at any moment with still intact circulatory, ventilatory subsystems.[56] In such circumstances, special tests for permanent cessation of the brain functioning will be needed. These special tests require total and permanent loss of all functioning of the brain stem and both hemispheres. They also require unresponsivity (deep coma), absent pupillary light reflexes, **apnea** (inability to breath), and absent brain reflexes. A new set of tests requires the demonstration that a lesion of the brain exists as well as tests disclosing the absence of cerebral blood flow. So when the tests confirm the permanent loss of the functioning of the brain or the brain stem, the doctor can turn off the mechanical ventilation, for, as Kennedy noted, "the ventilator is merely filling the corpse with air."[57]

However, there are cases of comatose patients whose brains are still functioning. These patients should be kept on ventilators until their brain death can be established. In a similar way, any person who suddenly stops breathing should be resuscitated, since, again, his or her brain death can not be determined at that particular time.[58] Many arguments support this position, but the strongest of these is the public confidence argument, since even if the basis of the decision not to resuscitate is reasonable, and that "the decision itself may not be intrinsically wrong, the consequences of such decisions are always bad."[59]

1-"public awareness that doctors do not resuscitate may undermine confidence in the profession."[60]

2- The slippery slope argument may be invoked. It can be asked, for example, if particular kind of patients are not resuscitated today, whose turn will it be tomorrow ?.

3- Nursing staff may tend not to continue attentive care, when they are informed that particular kinds of patients are not to be resuscitated.[61]

4- If the patient's family or relatives are asked to share responsibility for the decision not to resuscitate, they may decide so, either for the wrong reasons, i.e., according to their own interests, or for what may appear to them to be good reasons but still be left with life-long guilt about whether they have taken the right decision. Sometimes, people write their wishes on the matter of resuscitation in a "living will". In such cases the health care team is greatly assisted in solving the moral problems on this matter.

When considering the development of the embryo, it was said that the respect due to the embryo should be moulded by its stages of development. Similarly, with the brain decaying, there is "a

degeneration out of a person into living human tissue and back into the dust and ashes from which [he] came."[62] The human being must be respected in this process as well. Of course, the attitude of respect will not be that which is due to autonomous persons, rather that kind of respect due to human tissue.

(B) Mentally Handicapped Adult Persons, The Senile and Young Children:

It is not always possible to apply the analysis of the mature and rational adult (self-determining and self-governing person) to any of the individuals forming this group. For example, there are instances in which it is necessary to interfere with their decisions where it is obvious that their choice would harm them.[63]

It can be argued that the same situation may be met with a competent person. However, it is important to bear in mind that in the case of a mentally competent person, it is always possible to talk to him or her and warn him or her about the risks or drawbacks of any project. But when it comes to dealing with a severely mentally handicapped person or a child, one can not be sure that they have the capacity to understand their situations and therefore they can not be entirely allowed to decide for themselves. However, as has been noted,

> "the possible inability to understand is ... a matter of degree, but it may be reasonable to say that in extreme cases those without full measure of the distinctive endowment of a human being ought not to be given the same sort of treatment accorded to a rational adult."[64] (emphasis added)

Whatever justifies a diagnosis of mental illness, its effect is to

classify the individual so diagnosed as to some extent neither responsible for his or her actions nor capable of managing his or her affairs. But once again it is a matter of degree and each case must be treated to its own merits. No paternalistic interference can be permitted with the mentally handicapped person's decisions unless it is clear in their individual case and in the case of the particular decision in question that they are not maximally autonomous with respect to their decisions.

Similarly, as to whether or not particular children do not have the ability to make autonomous decisions and consequently must be protected will be "a question of judgment in each case exactly in the same way as it is for an adult."[65] But if the decisions of children are autonomous according to particular preferences, there is no need to interfere with them, i.e., they must be treated as if they were adults deciding in the same circumstances. For, the instability of their preferences is not a sufficient reason to justify paternalistic interference. Although it is known that children will change their views over time, this does not mean that their decisions are not fully autonomous, for it is argued that "to respect autonomy is to respect a person's decisions made in the light of their present character and priorities."[66]

1 : 4 CONCLUSIONS:

The main principle that should be observed in the doctor/patient relationship is that of respect for autonomy. The principle fully applies when one is dealing with a mature and rational adult, i.e., the adult person whose autonomy is not in doubt. There exists, however, a group of patients who are not in a position to act in a sufficiently autonomous manner because they either lack autonomy (the

embryo, the baby and the comatose patient) or have considerably impaired or otherwise inadequate autonomy (children and the mentally handicapped adult persons). But the impairment or the inadequacy of their autonomy do not necessarily mean that these patients must be denied the respect accorded to autonomous patients in all cases.

In this respect, it is important to reiterate the view that each case should be treated to its own merits and that no paternalistic interference with the decisions of patients forming these groups can be justified unless it is clear in their individual case and in the case of the particular decision in question that they are not maximally autonomous with respect to their decisions.

The brief discussion of these special groups of patients is meant only to acknowledge the existence of such kind of patients and that further discussion of these special situations is beyond the scope of the present thesis.[67] Alternatively, the present discussion will concentrate on the consent of the fully autonomous patient, and the ethical and practical problems that the issue raises in medical transactions.

The first step in framing the question is made in the second chapter and is concerned with the patient's rights, in particular, his or her right to consent to or refuse medical treatment which is said to flow directely from the patient's right to autonomy and self-determination and meant basically to protect it. In order, however, that cosent has this effect, the law requires that it must be real and therefore valid. Thus it is convenient to outline the main elements of a valid consent, how it could be evidenced and the role of the consent form or document.

Of major relevance to the present discussion is the law's role in protecting patients' rights and the mechanisms the law provides by

which grievances are redressed. Therefore it would be worth looking at some legal systems namely, the American and the British ones. The analysis of the law of consent in the American legal system will emphasize the development of the doctrine of informed consent, and this will be the task of the third chapter. Chapter four examines the issue under the British legal system.

The last two chapters will be concerned with the legal requirement of consent in the experimental setting. In an introductory chapter an exploration of some conceptual and ethical questions raised by human experimentation is in order. In the final chapter an analysis of the development of the law of consent to human experimentation will be outlined.

NOTES:

1-Katz, J., The Silent World of Doctor and Patient, New York, London, Free Press, Collier McMillan, 1984, p 104.

2-See Beauchamp, T. & Childress, J., Principles of Biomedical Ethics (2nd.ed), Oxford, O.U.P, 1983, p 59. Gillon, R., Philosophical Medical Ethics, London, Wiley & Sons, 1986, pp 60-66. Applbaum, P.S., Lidz, C.W. & Meisel, A., Informed Consent:legal theory and clinical practice, Oxford Uni. Press, 1987, PP 21-26. Faden, R. & Beauchamp, T., A History and Theory of Informed Consent, Oxford Univ. Press, 1986, Chapter 7 P 235.

3-Beauchamp and Childress, op.cit, p 59.

4-Ibid p 60.

5-Downie, R.S. & Calman, K.C., Healthy Respect: ethics in health care, London, Faber & Faber, 1987, pp 51.

6-Kant, E., Groundwork of the Metaphysic of moral, translated by Paton, H.P., New York, London, Harper & Row, 1964. p 30.

7-Mill, J.S., "Utilitarianism Liberty Representative Government", a selection from Acton P.H.B. (ed), August comte and positivism 1972, p 132.

8-Beauchamp and Childress, op.cit, p 61.

9-Id.

10-Ibid p 62.

11-See Downie and Calman, op.cit, p 53, Beauchamp and Childress, op.cit, p 62.

12-Beauchamp and Childress, op.cit, p 62.

13-Id.

14-Id.

15-Id.

16-"The Hippocratic Oath" in Beauchamp, T. & Walters, L. (eds)

"Contemporary Issues in Bioethics", California, Dickenson Pub.Com.Inc, Encino, 1978, p 138.

17-See Hart, H.L.A., The Concept of Law, Oxford, Clarendon Press, 1961, p 190, see also, Downie and Calman, op.cit, pp 46.

18-Downie and Calman, op.cit, p 47.

19-Gert, Bernard, The Moral Rules, New York, Free Press, 1972, p 125.

20-Ibid.

21-See Beauchamp and Childress, op.cit, p 109.

22-Ibid p 110.

23-Id.

24-D'arcy, E., Human Acts, Oxford, Clarendon Press, 1963.

25-at p 121..

26-Beauchamp and Childress, op.cit, p 110.

27-Prosser, W.L., Law of Torts, St.Paul, West.Pub.Comp, (4th.ed) 1971, p 145.

28-Notably, Downie and Calman, op.cit, p 47.

29-Ibid p 55.

30-Id.

31-For example, see Rawls, J., A theory of Justice, Oxford, Clarendon Press, 1972, p 3.

32-Beauchamp and Childress, op.cit, p 184.

33-Ibid.

34-See Gillon, op.cit, p 57.

35-Beauchamp and Childress, op.cit, p 20.

36-Ibid, see also, Downie and Calman, op.cit, p 57.

37-Id.

38-Id.

39-Notably, Downie and Calman, op.cit.

40-For further discussion see Harris, J., The Value of Life, London

Routledge and Kegan Paul, 1985, chap 1 pp 10, see also, Downie and Calman, op.cit, p 64.

41-Harris, op.cit, p 11.

42-Id.

43-Id.

44-See Downie and Calman, op.cit, p 65.

45-Report of the Committee of Inquiry Into Human Fertilization and Embryology, (Warnock Report), Cmnd 9314/1984. The committee recommended that experiments must be carried out during the first 14 days and by licenced bodies only.(para.11.22)

46-See Downie and Calman, op.cit, p 66.

47-Ibid p 185.

48-Ibid p 66.

49-See Veatch, R.M., A Theory of Medical Ethics, New York, Basic Books, 1985, p 242.

50-Harris, op.cit, p 240.

51-See Gert, B. & Culver, G., Philosophy in Medicine, Oxford University Press, 1982, p 181.

52-Veatch, R.M., op.cit, p 242.

53-Some require the permanent cessation of the functioning of the entire brain (U.S), others talk about the cessation of the functioning of the brain stem only (U.K).

54-See Gert and Culver, op.cit, p 186.

55-See Brazier, M., Medicine, Patients and the Law, Harmondsworth, Pelican Books, 1987, p 299.

56-See Culver and Gert, op.cit, p 188.

57-Kennedy, I., The Unmasking of Medicine, London, Allen and Unwin, 1981, p 157.

58-See Downie and Calman, op.cit, p 67.

59-Ibid p 69, original emphasis.

60-Id.

61-Ibid p 70.

62-Id.

63-Ibid p 71.

64-Id.

65-Harris, op.cit, p 215.

66-Id.

67-For a good discussion of these special groups, see McLean, S.A.M, "Disclosure of information, Consent to Medical treatment and the Law", Thesis, Glasgow University, 1987, also in her latest book, A Patient's Right to Know, Aldershot, Gower, 1989 Chapt 2.

CHAPTER TWO

NOTION OF VALID CONSENT

When considering autonomy and respect, it was argued that "to acknowledge another person is to acknowledge the possibility of other centers of choice and intention."[1] If the individual is seen as a self-determining moral agent, it follows that no interference is to take place with his or her physical and mental integrity without his or her prior agreement to that intervention. The right of the patient to consent to or refuse treatment derives from the principle of respect for autonomy or self-determination. The former analysis of the principle of autonomy made in the precedent chapter is relevant to the forcoming consideration of the patient's right to consent to medical procedures which is outlined in the following section.

2 : 1 THE RIGHT TO CONSENT TO MEDICAL TREATMENT:

It is known that in all medical transactions, one side, the patient, is vulnerable. The patient is short of the technical skills which are indispensable for curing himself or herself of any malady. Because of this deficiency patients are dependent on those who possess these technical skills and who are likely to bring them back to a state of health. One can appreciate the importance the individual attaches to health if one considers the fact that health means freedom from physical and mental sickness and the capacity to settle and determine one's present and future affairs. As has been said, health

"is also an area within which self-determination may

> be exercised. Indeed given the importance of health to individuals, it is of central importance to them that they have the capacity and the opportunity for choice in respect of medical intervention."[2]

This means that if the patient desires to retain his or her autonomy he or she must be allowed to accomplish his or her own wishes. This can be made possible only if the patient is given the opportunity to choose between different alternatives, i.e., he or she must be free to decide whether or not to consult a doctor and to choose between different kind of treatments, since it is only the patient who can determine which treatment or therapy is appropriate for him or her. It is often argued that choices and decisions that persons make in respect of their health, "are part of life choices, and therefore can not be readily removed from the would be autonomous individual."[3]

But sometimes, it is difficult for the individual to make up his or her own mind with respect to medical decisions or choices for these decisions may need to be made in circumstances where "clear, long-term thought, is difficult."[4] In addition, the assistance of the doctor, the possessor of the needed medical skill, confirms the difficult task of the patient in reaching an independent decision about his or her health care. This may constitute a real threat to the patient's autonomy which has an important role in any medical transaction. As has been said:

> "Nowhere in the interaction between doctor and patient is man's fundamental right to self-determination more clearly expressed, or more contentious, than in his right to provide or withhold consent to therapy or other medical intervention."[5]

The fact that the doctor has the needed technical skills does not

warrant to him or her permission to approach the patient without invitation. Thus the legal obligation to seek the valid consent of the patient constitutes a considerable protection to his or her bodily and mental integrity. Moreover, legally speaking the provision of a valid and meaningful consent is fundamental to the validity of the medical intervention. It is the patient's valid consent which renders legally permissible actions which could otherwise lead to a charge of assault.[6]

In fact, as has been noted, the provision of consent works in favour of both patient and doctor.[7] The patient, when exercising his or her right in making free decisions concerning his or her physical or mental integrity, is protected if he or she has the capacity to make such understanding decisions and choices about therapy. The doctor on the other hand protects himself or herself from any future allegation of unlawful touching by obtaining his or her patient's freely given consent. Apparently, therefore, it would surely be in the interests of both parties that a legally valid consent is obtained prior to any administration of treatment. In these terms, the provision of consent must be viewed as an enhancement to the doctor/patient relationship and a manifestation of the trust and respect which are essential elements in this relationship.

Nevertheless many believe that in order to have a successful medical transaction, the patient and only the patient is required to trust his or her doctor. As one scholar[8]pointed out, however, "trust may also...be perceived as a two way transaction."[9] In other words, the doctor can also be asked to trust his or her patient to deal appropriately with potentially distressing information and to make rational decisions which concern his or her physical and mental integrity. It is the acknowledgment of this element in the

doctor/patient relationship that renders the requirement of consent vital. It could also be viewed as the source of many of the disagreements and disputes between doctors and patients, because there are many doctors who are not in favour of the idea of discussing all that is involved in therapies with their patients. In fact, as has been observed, consent is

> "....both fundamental to, and highly problematic for, the doctor patient relationship. The implications of insufficiently or improperly obtained consent are often vital to to the general well being of the patient and thus to the medical, moral and legal aspects of medical practice. Consent is much more than a legal device or invention designed to intimidate medical practitioners....[it] is primarily derivative from a more general philosophical commitment to the essential right of the individual to make choices about what can and cannot be done with one's own body and mind."[10]

To put it another way, the legal obligation to obtain the consent of the individual reflects the accepted moral principle that each person has a right to self-determination and to physical and mental integrity. The breach of these principles usually leads to a general condemnation. A good illustration could be the international community's condemnation of the atrocities conducted by the Nazi physicians in the course of the second world war in the name of medical science and of the disrespect they had shown to these principles. Such an attitude confirms that the individual ought not to be approached for any kind of treatment or intervention without his or her actual consent. The provision of consent is central to the moral tone of the medical act. As explained above, the obvious inequality between doctors and patients in terms of medical knowledge and information, and the vulnerability of patients, make the obtaining of

the patient's valid consent a fundamental requirement. Equally, the observance of this legal requirement can be viewed as a manifestation of respect for patient's autonomy.

However, if the patient is to make a free and understanding decision or choice either to consent to or to withhold particular treatment, he or she must satisfy some moral and legal requirements. Most of these requirements are related to the elements of real or valid consent which will be considered later in this discussion. The main point to note at this stage, however, is that there is no specific way in which consent may be expressed.[11] What is important, in fact, is the manner in which the patient reaches his or her decision to consent to the treatment being administered.

For some scholars[12] the patient may be said to consent to medical treatment merely by consulting the practitioner. This conclusion is drawn from the fact that the individual presents himself or herself voluntarily to the doctor for examination. That is, it is often claimed that in the medical context consent is taken as "a parallel with the notion of tacit consent as sometimes applied in political philosophy".[13]

In politics, consent is the basis of any political obligation.[14] Given the circumstances, however, it is practically impossible to obtain the express consent of each individual citizen. Hence most theorists rely on tacit consent which is usually given "passively by omissions and by failures to indicate or signify dissent."[15] For example, during the meeting of the company's board, the chairman announces a change in the time of the next meeting and asks whether there is any objection. The board members do not raise any objection. In so doing they have all tacitly consented to the chairman's proposal.

It is argued[16], however, that the mere invitation to exercise the technical skills possessed by the doctor and to reach a diagnosis do not lead to a provision of consent, at least not a proper one, to the particular treatment or therapy that the physician may believe is suitable to the condition of the patient. For even in the doctrine of tacit consent, the potential consentor's silence is meaningful only if he or she understands his or her situation and is aware of what is happening.[17] Moreover, consultations may be equal to consent only when the individual seeks the prescription of a common drug whose characteristics and side effects are generally known. For if one asserts that consultation equals consent in all instances, it necessary follows that in cases where the therapies are more intrusive, the patient's consent is already obtained. In fact, a real consent requires more than the simple fact of presenting oneself to the physician for consultation. A real consent must be based on the disclosure of information which permits the patient to make a decision about whether or not to accept the proposed treatment. This can only be made possible if the individual is provided with the information on which he or she can decide how to act. Therefore, it can be concluded that in medical practice, implied or tacit consent can not be considered valid consents unless the individual concerned is presented with an appropriate disclosure of information which enables him or her to make a rational decision as to whether to undergo the proposed treatment.[18]

In cases where a sufficient amount of information has been disclosed and the patient accepts the treatment, as in the case of a prescription, the patient consents implicitly by his or her taking the prescription and buying the drugs. That is, what is important in the whole issue is the basis on which the patient's acceptance is reached,

i.e., the reasonableness and adequacy of information on which the patient made his or her decision to follow his or her doctor's recommendations. As has been said;

> "What is fundamental to the provision of consent is the protection of the freedom of the individual to make choices, and therefore, what functionally makes consent valid is that aspect of it which is sometimes referred to as being knowledgeable."[19]

In contemporary legal discussions about consent in medical practice, the requirement that consent is based on information disclosure has been labelled 'informed consent' and is legally speaking as essential as care and skill in the performance of the treatment.

The description of consent by this concept is the product of American medical law. This concept has its roots in a recognition of the patient's right to self-determination. It suggests, as will be seen later, that a doctor is required to provide the patient with sufficient information which concerns the nature of the treatment, inherent risks, and the available alternatives, so that the patient can make an 'informed' or rational choice as to whether to undergo the proposed treatment. Therefore a general or a blanket consent may have no legal force, if the patient was not given a chance to compare the risks of undergoing treatment with the danger of foregoing it. The patient must be given a comprehensible explanation of the treatment in question in language which must be as simple and as nontechnical as is possible in all the circumstances.[20] Even if the patient signs a form containing a statement by him or her that the nature and the effects of the treatment have been explained to him or her, this would not prevent him or her from later claiming that a comprehensible

explanation had not been given.

In British law, the concept of 'informed consent' is not adopted, and the term 'informed' is hardly used. In fact it seems to be used in only one reported case (Re.D "A Minor")[21]. This does not mean, however, that British courts have no concern for consent nor that current legal doctrine has no implications about disclosure. As was said in Hills v. Potter[22];

> "...it is quite clear from the English cases...that on any view English law does require the surgeon to supply to the patient information to enable the plaintiff to decide whether or not to undergo the operation."[23]

That is to say that under English law the doctor is required to explain the nature and purpose of the proposed therapy, i.e., a duty corresponding to the transatlantic doctrine of 'informed consent'.[24] The first English case supporting the existence of such a duty was Chatterton v. Gerson.[25]

In sum, it can be safely said at this stage that legal systems agree to the fact that only by making a reasonable and comprehensible disclosure of information can patient autonomy be protected.

(A) THE REQUIREMENT OF CONSENT IN HUMAN EXPERIMENTATION:

The requirement of consent is also a fundamental condition of any medical research involving human subjects. The first imposition of rules requiring consent in this area of medicine took place in 1948 as part of the judgment in United States v. Karl Brandl[26], the Nuremberg trial of Nazi physicians who engaged in biomedical experiments during the second world war.

Although it was a common misconception that these were the

earliest examples of willfully harmful, vicious research on unwilling human subjects, the Nazi experiments were in many aspects unprecedented in the extensiveness and extremity of the harm and suffering to which they knowingly exposed their victims. Using subjects drawn from the populations of concentration camps, Nazi scientists explored the effects of ingesting poisons, intravenous injections of **Gasiodine**, immersion in ice water and the like. Infection with epidemic jaundice and other viruses were typical parts of medical experiments.

At the trial it was evident that in no respect could the victims of the Nazi experiments qualify as volunteers, much less as informed volunteers. The tribunal was satisfied that the defendants had corrupted the ethics of the medical profession in particular, and those of science in general, and had repeatedly and deliberately violated their subjects'rights. The judges gave a central role to the voluntary participation and consent of research subjects regardless of whether it was common professional practice among physician-investigators to seek consent. Specifically, the judges took responsibility for establishing the basic principles that must be observed in order to satisfy moral, ethical and legal concepts in the conduct of human subject research. These principles were ten in all and constituted the Nuremberg Code.

According to the Code the primary consideration in research is the subject's voluntary consent, which is absolutely essential. It requires that consent have at least four characteristics; it must be voluntary, competent, informed and comprehending.[27]

In in 1964 the World Medical Association adopted the Declaration of Helsinki whose recommendations were extended in Tokyo in 1974.

Like the Nuremberg Code, the Declaration of Helsinki provided a

useful ethical and legal framework whithin which human research can be conducted, and also emphasised the requirement of valid consent.

By and large, international agreements make it a prerequisite of professional care either in therapy or human research that doctors seek their patients' freely given consent following a sufficient disclosure of information. It should be reiterated that this requirement is tied to the idea that the patient's right to consent to or refuse medical intervention is of considerable importance for the would be autonomous person. As has been pointed out, consent is valued because of its

> "capacity to protect the individual patient from his or her vulnerability to the power of medicine and stimulates his or her capacity to challenge professional paternalism which, however well intentioned, can be and often is a face-on threat to autonomy."[28]

Patients' rights, including autonomy, are usually protected by the law which recognises their significance as legal and moral rights. By means of rules and the determination of rights and duties the law assures a proper exercise of rights and provides the machinery by which their infringement can be remedied.

(B) MECHANISMS OF LEGAL REDRESS:

In the medical context, legal systems provide the patient with different forms of action to register a complaint when his or her rights are not respected. Under the U.K system, for instance, it was possible to base one's action on assault when the patient was not satisfied about the given treatment or was approached without his or her real consent. However, in recent years there has been an important shift away from the assault based action into the negligence

format. This shift will be considered in later chapters, but it is worth noting at this stage that as the patient is certainly the person most affected by the malady, it is he or she who has the ultimate right to make decisions about his or her health care, and consequently, no interference should take place with his or her right to determine his or her future in matters relating to his or her health care. Failure to respect these basic rights may result in a legal action against the practitioner.

2 : 2 IS CONSENT ALWAYS NECESSARY ?

This is not to say, however, that the provision of consent as a legal requirement is always necessary for any medical intervention. There are cases where consent is generally recognized as unnecessary, for example in cases of emergency or necessity. However, there is some doubt here whether these are to be taken as cases of implied consent where express consent is impossible as in the case where the patient is unconscious, or just as an overriding principle which abolishes the need for consent. This problem may arise in two ways:

1-The physician treats a patient in an emergency without any prior authorization.

2-The physician is authorised by the patient to perform one course of treatment, in the course of which he or she discovers an unanticipated emergency condition substantially unrelated to the condition he or she is treating which requires immediate attention in circumstances where it is impossible and impractible to to obtain the patient's consent. In the Canadian case of Marshall v. Curry[29], Chisholm, J said :

> "In these emergency cases it is not useful to strain the law by establishing consent by fictions-by basing

consent on things that do not exist. Is it not better to decide boldly that apart from any consent the conditions discovered make it imperative on the part of the doctor to operate, and if he performs the duty skilfully and with due prudence that no action shall lie against him for doing so."[30]

Chisholm's statement seems to be a more logical explanation than a fictional imputation of consent, but does it mean that a patient who urgently needs medical treatment cannot refuse it.?

In effect, experiences have shown that patients and subjects with the capacity to consent may refuse instead. The refusal, however, must also be competent, voluntary and informed.[31]

Although refusals can occur in non life - threatening circumstances, the major controversies emerge from refusals of medical therapy necessary to sustain life. Examples include refusals to allow blood transfusions, amputations or kidney dialysis. While patients have refused treatment, such as blood transfusions, because of their religious convictions, the right to autonomy and privacy are often invoked to justify refusals for non religious and even highly esoteric reasons. There are also problems of second party refusal in the case of children and certain classes of incompetent patient

In discussing the issue a distinction is to be drawn between the refusal of competent patients and that of the incompetent or their guardians.

First, refusals by competent adult patients usually raise the question "what are the implications and limits of the principle of autonomy ?"

It is recognised that the patient, if of sound mind, can expressly prohibit the performance of life saving surgery. This can be reconciled with the principle of freedom and self-determination which

is fundamental in Anglo-American legal systems.[32] In the crucial legal decision which set the standards for 'informed consent' in the 1960s, Kansas Supreme Court Justice Alfred Schroender declared:

> "Anglo-American law starts with the premise of thorough-going self-determination. It follows that each man is considered to be master of his own body, and he may if he be of sound mind expressly prohibit the performance of life saving surgery or other medical treatment. A doctor may well believe that an operation or form of treatment is desirable or necessary, but the law does not permit him to substitute his own judgment for that of the patient by any form or artifice or deception."[33]

In practice a number of precedent legal cases hold that the patient's informed refusal should be decisive. In Erickson V. Dilgard[34], for instance, Judge Meyer acknowledged that the court will step in as guardian of an infant or an incompetent, but in this case the patient was completely competent and capable of making decisions on his own behalf. The judge said:

> "It is the individual who is the subject of a medical decision who has the final say....this must be necessarily so in a system of government which gives the greatest possible protection to the individual in the furtherance of his own desires."[35]

That is to say, the individual's self-determination was considered as an inviolable right. In another case, namely, Re Estate of Brooks[36] the free exercise of religion was regarded as a sufficient reason to prevent physicians from compelling the therapy if there is a competent refusal.

Second, concerning the refusal of an incompetent person, or his or her guardian, to any life-saving treatment, it is generally agreed

that guardian may not refuse a treatment that would restore reasonably normal health. In these cases the courts hold that the freedom of religion does not give parents or guardians the right to endanger the life of their children.[37] Courts, however, may accept the refusal of parents or guardians if the refusal is reasonable. Three grounds appear to be acceptable for refusing treatment.

1- A refusal will be reasonable if the risk of the proposed treatment is substantial in comparison to benefits.[38]

2- It will be reasonable if there is a lack of a clear need for treatment.[39]

3- A third ground for a reasonable refusal is that in non-emergency cases, particularly those involving older minors, the treatment can wait until the minor becomes competent to be consulted.[40]

Finally, the refusal of medical treatment may arise in accidents and other emergency cases not from the patient himself - because of his or her state of unconsciousness- but from a relative or spouse.

It is argued that there exist no grounds on which any relative has the right to refuse to allow a patient to receive necessary medical treatment. Consequently, if the spouse or near relative does not purport to be expressing the patient's own wishes, there seems to be no alternative but to disregard the purported prohibition. However, if the spouse or near relative purports to be conveying what he or she believes to be the patient's own wishes, a different situation arises, since the law still appears to be that no procedure can be proceeded with contrary to the patient's wishes.

When an operation is done in an emergency without consent, physicians act as agents of necessity to do what it is assumed a reasonable person in the patient's predicament would want done for him

or for her, and this presumption is not rebutted by the information given by the spouse or relative, since there is no certainty that if the patient were told,"either you have this procedure carried out or you will be in danger of almost certain death", he or she would refuse consent to the recommended procedure. Therefore, if a blood transfusion or any other medical treatment is necessary to attempt to save life, it should as a rule still be carried out despite objection by a spouse or relative, even if in objecting that person purports to be expressing what he or she thinks to be the patient's wishes.

In sum, it can be said that under normal circumstances a doctor can not properly undertake any treatment without the prior consent of his or her patient. Failure to do so may expose the doctor to the risk of being sued for assault or battery. An exception is made, however, in cases of emergencies which require immediate treatment. It is recognised that an operation done without the consent of the patient is lawful only if necessary to preserve the life or the health of the patient. What are then the implications of the patient's consent when it is obtained properly ?. The next section examines the point.

2 : 3 DEFINITION and NATURE of CONSENT:

Consent could be defined as "the granting to someone the permission to do something he [or she] would not have the right to do without such permission"[41]. Defined this way, consent acts as an absolute defence to an action in tort/delict based on the unlawful touching of the individual's body. But in order to understand the nature of consent, it is important first to have some understanding of the legal relationship between the doctor and his or her patient. This relationship is contractual by nature. Usually, the contract is formed by implication when the parties reach an agreement as to what

will be done. In the same way, the acts to be performed by them are also impliedly defined. For instance, if an individual consults the surgeon for the removal of a tumor from his or her arm, a contract is formed in which the surgeon is under a legal duty to remove the tumor and he or she should not go beyond that agreement and also remove the patient's appendix. That is to say, the surgeon must act in accordance with the agreement made between him or her and the patient. The patient's consent is usually given in connection with what the parties agreed to be done. Therefore, if the surgeon removes the appendix as well, as in the example above, he or she must be liable in damages.

But it should be noted in this respect that unlike the general position in the criminal law, consent may be used as a defence in the civil law. In criminal allegations, the nature of a charge, e.g., murder, cannot under any circumstances be changed by appeal to the victim's consent.[42]. Accordingly, voluntary euthanasia still is a criminal offence. This implication is drawn from the fact that "the behaviour involved in the act is struck at by the law on the grounds that it is in itself morally reprehensible"[43]. There is only one situation where the provision of consent can be used as a defence in the criminal law, and that is when the lack of consent is "central to the nature and quality of the act".[44] For instance, if it can reasonably be shown that a woman consents to intercourse, this can constitute a sufficient defence against a charge of rape.[45]

It is important to bear in mind, however, that medical practice is governed by the civil law in which consent as a legal doctrine arises in two forms;

(I)-Active consent: the meaning of consent in this form is the granting to someone of the permission to invade one's own rights or

interests which in the absence of such permission would be construed as a delict/tort, for example, the performance of an operation on one's body.

(II)-The second form is the assumption of risk, or the maxim *volenti non fit injuria.* The significance of this maxim is that it expresses the idea that a person who agrees to the infliction upon himself or herself of a civil wrong can not recover in respect of any injury to which he or she has consented, any more than anyone can recover in respect of any injury which he himself or she herself, rather than the defendant, has caused.[46] Therefore, although medical practice may require that the physician performs some actions, e.g., surgery or amputation, which in other circumstances would constitute assaults, the free and knowing consent of the patient will render these actions lawful. Moreover, when the patient accepts voluntarily the performance of certain actions on his or her body, based on a reasonable disclosure of information, he or she can not later successfully sue his or her doctor should any of the risks he or she was warned of, and which he or she agreed to assume, actually materialize.

However, if the maxim is to be successfully applied as a defence, it must be proved that the party freely and voluntarily, with full knowledge of the nature and extent of the risk he or she ran, impliedly or expressly agreed to incur it. However, this requires again that the nature of the risk which the party agreed to incur, is known or explicable. As Walker said;

> "If the plea is to succeed, it must be shown not that the pursuer consented to take the risk of some harm befalling him, but he consented to take the risk of the particular kind of harm which in fact befell him."[47]

Usually, the patient's consent is sought before the doctor may intervene. Accordingly, when the patient gives his or her real consent, this consent is a defence to any allegation based on assault. In medical transactions, by the voluntary provision of consent, the patient shifts his or her right to bodily and mental integrity to another person, usually a caring professional. This means;

first, consent that shifts a right to another person must be distinguished from a mere attitude of approval. As Childress[48] illustrated it, one may approve of a particular research protocol involving human subjects, but one may still refuse to participate in it. The person's consent, as distinct from his or her approval, is a necessary and vital condition for the research to be carried out with him or her as a subject.

Second, consent is an intentional act. No one can consent to or authorise another person's actions without doing so intentionally. To consent intentionally to the actions of another person means that the consenting person is aware and knows what he or she is agreeing to. Even if the patient, or the subject of a research project, signs a consent form, this does not constitute a real and valid consent if he or she does not know what it is all about, for the patient may later repudiate the consent form on the grounds that he or she has not understood what it was he or she was signing. Moreover, as Kloss[49] pointed out, consent must not be obtained by using a "blank cheque", or without a sufficient and reasonable disclosure of information, since in these cases the doctor obtains <u>an apparent consent</u> not <u>a real consent</u> and this may constitute a sufficient ground to found an action in negligence for the breach of the doctor's duty toward his or her patient. As has been said "the law inquires not whether the patient appeared to be willing but whether he was willing"[50].

Third, consent must be given voluntarily; a consent given under duress is not a real or valid consent and "does not change the structure of rights and obligations"[51]. For instance, if a woman consents to sexual intercourse under duress, her consent will not exonerate the criminal from the charge of rape.

Fourth, consent does not necessarily involve oral or written statements. Nobody denies the utility of written authorization when consent is presented in such a formal way (consent forms), but such forms are not indispensible for the carrying out of medical treatments. There are cases where, although the patient is conscious, he or she can not communicate either by writing or speaking. An example of this arose in a case quoted from "The Daily Progress", Charlotteville; Va, Sep 19th 1979, where the patient though conscious could not speak because of a tube in her windpipe. She blinked her eyes twice to indicate that she did not want a blood transfusion. This shows that certain actions and gestures can be used to evidence or indicate the person's consent or refusal.

(A) COMPULSORY MEDICAL EXAMINATION:

So far, concentration has been on the nature and characteristics of consent. It was argued that if consent is to be used as a defence by a doctor this consent must be real and valid and must stem from the knowledge and understanding of all that it involves. This can be reconciled with the common law's principle that every person has the right to have his or her bodily integrity protected against invasion by others[52]. There are, however, certain circumstances in which this integrity may be compromised without the consent of the person. Examples include the carrying out of medical attention without consent

in cases of emergencies in order to save lives[53] and cases of compulsory medical examination. In effect there are some special circumstances in which a person can be submitted to medical examination without his or her consent. However, even under these circumstances, the doctor must not go beyond the mere ordinary physical or mental examination or the administration of the specific treatment sanctioned by the law.

1-Public Health; the law may require that certain kinds of treatment be proceeded with compulsorily in order to protect all members of society as a whole. Accordingly, citizens may be compelled to receive vaccination to prevent certain diseases. In these cases the individual has no right either to give or to refuse consent, but still has the right to choose the doctor who is to perform the treatment in question[54]. Moreover, a person who has a notifiable disease or is carrying an organism capable of causing one, may be ordered to be medically examined and removed to hospital and detained there if necessary (Infectious Diseases and the Public Health, Control of Diseases, Act 1984, SS 35-38), (Public Health, Infectious Diseases, Regulations 1968(SI 68/1366 as amended).

It should be noted that the Public Health (Infectious Diseases) regulations 1985 (Si 85/434) did not make AIDS notifiable. It was reasoned that that would impose unacceptable restrictions on sufferers, including, for example, restrictions in their use of public transport, when in fact the virus is not particularly infectious. Nevertheless, a local authority can obtain an order from a magistrate under S.38 of the Act for the detention in hospital of any patient with AIDS where there is evidence that proper precautions would not be taken by him or her on his or her discharge to prevent the spread of

the disease. In addition the AIDS (Control) Act 1987 requires authorities to furnish periodic reports on AIDS patients.

2-Prisoners; persons kept in prisons must submit to routine physical examination. The reason for this procedure is understandable; in such closed communities infections may easily be introduced and spread and this can have serious consequences for all people involved in these institutions. It is important to note that this compulsory medical examination does not extend to intimate examinations. There must be a real consent to that effect, and the same is true in respect of the taking of blood samples from prisoners.

3-IMMIGRANTS: for the same reason outlined in the case of prisoners, port and airport medical officers have the authority to compel any immigrant to submit to an examination, if they consider it necessary, in order to exclude infections.

When it is appropriate to seek the person's consent, this can be obtain either impliedly or expressly. The point was already made, however, that when the treatment is invasive mere consultation is not sufficient to evidence the patient's consent and that a proper consent must be obtained based on information disclosure. The different forms of providing consent are examined below with illustrations.

2 : 4 FORMS OF CONSENT:

There are instances in which consent need not be presented in a formal way, i.e., written or spoken.[55] Consent may be 'implied' or 'express' and the latter may be given verbally or in a written form.[56]

Express consent can be given either by a signing of a written

statement or by agreeing in words, so that any reasonable person would conclude that the patient agrees to the proposed treatment. Implied consent, however, is not expressed at all, it is rather inferred from the actions or from the person's conduct, where his or her conduct is such that one would naturally conclude from his or her behaviour and the surrounding circumstances of a given situation that he or she agrees to the act being performed or to the treatment being administered. For instance, consent is given impliedly when a person presents himself or herself for a medical examination; he or she agrees to what is necessary to carry out the proper examination in question. But it is important to bear in mind that consent in this form does not permit any other step beyond an ordinary physical examination of the patient. For example, it does not extend to the performance of intimate examinations,[57] or to a more invasive procedure. This is to say that there are limits to what an individual can be thought to have consented to by having a consultation. Failure to obtain a proper consent from the patient can result in the doctor being sued either on the basis of unlawful touching due to the lack of consent, or for negligence if the doctor fails to disclose information about the treatment. In Devi v. West Midlands Regional Health Authority [58], a woman consented to a minor operation on her womb. On the basis of this consent, the surgeon proceeded with a major operation of sterilisation which he thought was necessary. In ordering damages for the plaintiff patient, the court held that the woman's consent to the first operation was not sufficient to go ahead with a more serious operation and that the operation itself was not necessary for the preservation of the life of the woman. The surgeon could have postponed the operation until his patient's consent was sought, even though it was convenient to operate when the patient was

still under anaesthetic. This is to say that the physician must act according to what the patient consents to be done to his or her body, and that mere consultation of the physician is not sufficient grounds for the doctor to assume the patient's consent and proceed with the appropriate treatment without disclosing information or obtaining a real consent for the proposed treatment. The patient may consent to the course of a given treatment and either impliedly or expressly make a restriction thereon or give express instructions. In this case the doctor must comply with these instructions, otherwise his or her interference with the patient's body will be held to be tortious/delictual. In Rolater v. Strain[59], the plaintiff patient made it clear that she didn't want to have any bones removed when the defendant surgeon operated on her to drain a puncture wound in her foot. Despite the express restriction and prohibition the defendant removed a sesamoid bone. In deciding in favour of the plaintiff, the court held that when a physician agrees to perform a certain course of action, he or she is bound to such agreement unless there are some unusual circumstances from which consent can be implied regardless of the prohibition. Similarly, in Mulloy v.Hop Sang[60], the physician was requested to repair an injured hand and not to amputate it. Again despite the warning the surgeon amputated it and was held liable for trespass.

As mentioned before, both express and implied consent are legally sufficient for the carrying out of any medical treatment. However, where express consent is sought, there are obvious advantages in obtaining it in writing.[61] This raises the issue of the signing of the consent form on admission to Hospital or prior to surgical interventions.

2:5 THE CONSENT FORM:

It is common practice to obtain the patient's signature on consent forms especially when the Hospital regulations make it a prerequisite condition precedent to the performance of any procedure. A signed consent form means that the patient has been made aware about the nature and purpose of the proposed treatment. But usually it is a nurse who obtains the patient's signature on the consent form, and the nurse is unlikely to provide the patient with an adequate disclosure of information about his or her treatment. The nurse merely mentions that a signed consent form is necessary.[62] Under these circumstances the signed document is not conclusive evidence that the patient has been provided with the needed information on which to base a real consent. This is to say that even if the patient signs a consent form which contains a statement by the patient that the nature and effects of the treatment have been explained to him or her, nothing would prevent him or her from later claiming that he or she has not actually received an adequate disclosure of information and explanation.[63] The written document should contain at least "the nature of the treatment and its side effects", "the methods used in the trial", "the stage of the patient's illness" and "the importance of the personal nature of the doctor/patient relationship."[64]

Under British law a standard form has been made available by the Department of Health in cooperation with the Department of Social Security, the British Medical Association, the Medical Defence Union and the Medical Protection Society. The form is some kind of evidence that the patient consents to the treatment being performed on his or her body, and is usually required for surgical intervention. The form contains a statement that the patient also consents to further procedures or measures that may be found necessary.[65] However the

doctor is allowed to undertake only those procedures that may save the life or the health of the patient. It would be unwise to go ahead with further procedures that could be postponed to a later stage and until the patient's consent is obtained.

Recently, in Sept. 1988, the Department of Health put at the disposition of Hospitals three proposed new consent forms; ones to be used in medical and dental treatment and others to be used specifically for vasectomy and female sterilization. The proposed new consent form has a space where the caring professional, whether doctor or dentist, should sign a statement that he or she has explained the treatment to his or her patient or to the patient's guardian in case of proxy consent, that he or she has mentioned the need for the administration of an anesthetic if required, and finally that he or she reasonably believes that the patient has assimilated the disclosed information.

The patient on the other hand has to sign, on the same document, a statement that he or she has received the due explanation , that he or she understands that the treatment will not necessarily be performed by the specific doctor and that he or she authorizes further measures that may be found necessary during the performance of the intended treatment. Again, the further measures are not to be proceeded with unless they are necessary to save the patient's life or health.

In any event the consent form should not be considered merely as a legal device to protect the doctor from subsequent litigation, rather it must be considered as an extension to the doctor/patient relationship that is built on trust, and the provision of consent, whether verbally or in a written form, must be seen as "a natural extension of the trust established".[66]

Earlier in this chapter, it was mentioned that for consent to be

meaningful and/or to be used as a defence by a doctor, it must be a real and valid consent, and must stem from knowledge and understanding about all that it involves. The point has now been reached where it is necessary to consider what amounts to a valid consent. The following discussion will therfore be concerned with the elements of a valid consent.

2:6 ELEMENTS OF VALID CONSENT:

A valid consent is formed of two main elements:

1-Information element: this contains;

A-Disclosure of information: the patient has the right to be provided with certain information. Correlatively, the doctor is under a legal duty to disclose this information on the basis of which the patient decides whether or not to consent to the proposed treatment. In general patients are thought to know at least certain information. Others may be presumed to be aware of additional information on the basis of personal experience. This raises the question of what needs to be disclosed and which standard is to be used in determining the adequacy of the explanation given

B-Comprehension of information: generally, the patient can not be said to have given a real consent unless he or she understands the information that the doctor is under a legal duty to disclose. Of course the disclosure of information should be done in a certain manner to ensure that the patient understands what he or she is told. But, is the doctor responsible for the patient's inability to understand the information.?

2-Consent elements:

C-Voluntariness; the consent must be freely granted and not obtained by force, fraud, coercion or mistake.

D-Competence; the patient must be a competent person to give a valid consent. Generally, only adult, sane persons are believed to have the capacity to consent to treatment, but there are borderline cases.

INFORMATION ELEMENTS

A-DISCLOSURE OF INFORMATION:

The disclosure of information is the first important element of a valid consent. It is a manifestation of the respect due to the autonomy of the patient and to his or her right to make a rational decision about the future of his or her health care. Before considering different elements of disclosure, it will be convenient to say a word about certain factors that affect the amount of information that should be disclosed.

The law is well settled that the physician should deal honestly with his or her patient in terms of providing the patient with the necessary information to make a rational decision. But it does not follow that the doctor is obliged to give all the details of the procedure or to warm the patient about any risk however remote it may be, for this may only distress and frighten the patient, and prevent him or her from undergoing the procedure.[67] This is to say that when the doctor reasonably believes that the giving of certain information will have a directly detrimental effect on the patient's health, he or she will not be in breach of duty if he or she does not disclose this information. Therefore, the likely effect of information on the patient should be taken into consideration when disclosing

information[68]. It is assumed in the example above that the procedure is intended for the benefit of the patient's health, for it is often argued that when the treatment is not intended for the benefit of the patient's health, e,g subjecting the patient to non-therapeutic experimentation, the patient must be given a full disclosure of all the factors that are necessary for him or her to to decide whether to consent. In addition to what physicians believe to be relevant, the disclosure must include any other piece of information that the particular patient would prefer to know before agreeing to the treatment or the experiment.[69]

First, the patient's capacity to understand the information and make a rational decision on the basis of this information also determines the amount of information to be disclosed; if the patient's capacity to understand is restricted, the amount of explanation will be much less than if the patient shows a greater capacity to comprehend.

Second, the extent to which the patient desires to be informed affects to some extent the amount of information to be given; if the patient desires not to be informed and leaves all the decisions to his or her physician, it is his or her right if he or she wishes to do so. But if the patient asks for certain information the doctor must tell him or her.

Finally, the likely occurrence of risks; when some risks are likely to occur during the course, or after the performance, of the treatment, or are known to have serious consequences, the doctor's duty to mention them is much greater than if these risks are remote or of little consequence.

B: ELEMENTS OF DISCLOSURE:

As stated before, the physician is under a legal duty to disclose certain information about the nature of the treatment, the benefits or the results expected, the risks inherent in the treatment and the alternatives.[70] These elements define the nature and the scope of the duty of the physician to make sure that the patient consents to the proposed therapy in light of information relevant to that decision.

1-The nature of the procedure; the law requires that physicians explain the nature of the therapy to their patients in order to obtain a meaningful and valid consent from them. The nature of the treatment can be characterized in different ways; the physician has to explain whether the procedure is diagnostic or therapeutic, for the surgeon may operate on the patient in order to find out what is wrong with him or her. In this case the surgeon has to explain this fact, since the majority of patients may think that the surgeon's intervention is meant to bring relief from suffering.[71] The doctor has also to explain whether the procedure is invasive or not, i.e., does the procedure involve a physical touching or an entry into their body, e.g., Angriography. Part of the nature of the treatment is the duration of the treatment and the need for anaesthesia. It is also essential to tell the patient whether the procedure is therapeutic or merely a part of a research protocol.

2-Disclosure of risks inherent in the treatment; most allegations of unlawful medical touching or administration of treatment are based on the failure to warn of the risks involved in the treatment.[72] Ethically, the matter is related to the person's right to self-

determination. As far as morality is concerned, a person is not to be exposed to a risk if he or she has not agreed to it. This makes the warning of risks that may occur in the procedure one of the most emphasized elements of information disclosure.

In effect, knowledge of the risks is essential for the patient in order fully to understand the therapy, since it is on the basis of the disclosure of these risks and the likelihood of their occurrence that the patient decides whether to undergo the treatment or to go on living without such treatment in cases where it is the only alternative.

In determining the risks that should be disclosed or warned of, the doctor has to refer to the applicable or prevailing standard of disclosure. In the U.S.A courts and legislatures very often distinguish among material[73], substantial[74], probable[75] and significant[76] risks. Under British law, as will be seen later, courts require the disclosure of 'real' risk.[77]

It should be noted that disclosure of risks must include; the nature of the risk, its seriousness and the probability of occurrence. If ,however, the probability of occurrence is extremely low, nondisclosure may be justifiable. In a similar way, if a risk is likely to occur, but with little consequence, nondisclosure may again be justifiable.[78]

Mention was made earlier that the physician should take into account the likely effect of the disclosure of information on the patient. It was said that the doctor is privileged to withhold disclosure when it is likely to cause the patient distress and confusion. However, it must be borne in mind that "this is not the same thing as deciding to withhold information which it is thought would lead the patient to refuse the treatment. The latter practice is

hardly acceptable ethically".[79] As has been said, the patient as a free agent has a right to make even a wrong decision.[80]

However, some scholars are against the practice of 'therapeutic privilege', even when the information is likely to cause harm. For example, Buchanan[81] noted that the physician can hardly determine which information will be to the detriment of the patient's health, since the determination of this depends to some extent on factors personal to the patient and outside the medical context. Moreover, if the doctor believes, he argued, that the disclosure of a certain risk or information is very likely to be psychologically detrimental, he or she has also to make sure that withholding this information will not do a greater harm to the patient in comparison to the harm that may occur when giving the information.

3-Alternatives; it is argued that the disclosure of alternatives to proposed treatment is as essential as the warning of risks to medical decision making. Usually, the physician proposes the treatment that he or she believes to be the best for the patient's condition. This means that any other procedures have less value from the medical point of view. However, decision making in health care is not based on medical grounds alone. There are other factors which should be taken into consideration. These concern the patient's values, preferences, goals and needs. The patient may choose a course of treatment which can be less successful than the one proposed by the doctor but this decision must still be respected.

To make a rational choice requires that physicians also disclose the other alternatives to the recommended treatment. The disclosure of alternatives should include the nature and purpose of these options as well as their risks and benefits.[82] With such information, the

patient will be able to compare and evaluate medical risks and benefits according to his or her personal considerations. Sometimes, there may be alternatives of the same value, or it is difficult to determine objectively which procedure is preferable to another. But in any event, there is still the alternative of no treatment at all.

4-Benefits; although it is part of the physician's legal duty to enumerate the benefits expected from the proposed treatment, these are self-evident and can be understood from the purpose of the procedure, i.e., to bring relief to his or her suffering and troubles. Accordingly, when the patient asks for relief or anticipates that the proposed treatment will bring total relief to his or her suffering, the disclosure of benefits is not so important.

There are, however, two cases in which the disclosure of benefits is fundamental.[83]

1- When the purpose of the treatment or procedure is merely diagnostic rather than therapeutic. In such case, the patient must be informed that the procedure is not meant to bring any relief but rather is intended to provide some information as to how to proceed with other therapeutic procedures.

2- The disclosure of benefits expected from the recommended treatment can also be important when the purpose of the treatment is to bring only some relief to the patient's condition.

C: Standards of Disclosure:

The standard of disclosure is "the standard by which the adequacy of the physician's disclosure is measured, thus allowing the fact finder to evaluate whether the duty of disclosure has been fulfilled".[84]

Following the birth of the doctrine of informed consent in the U.S.A, courts generally adopted a professional standard in determining the scope of disclosure that should be made to patients. Accordingly, a physician will fulfill his or her duty of disclosure if the disclosure he or she has made equals the one that a reasonable medical practitioner would make under similar circumstances.[85]

However, in Canterbury v. Spence [86], the court enunciated the "prudent patient" test for determining the scope of disclosure of information, and in particular, information concerned with material risks.

> "A risk is thus material 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 determining whether or not to forgo the proposed treatment"[87]

However, it should be noted that both standards are in use in the U.S.A. Some states, have preferred to adopt the test enunciated in *Canterbury* (prudent patient), whereas the majority apply the "reasonable doctor" test.[88] Canadian courts also have opted for the "prudent patient" test for determining the scope of disclosure that should be made by physicians. In this respect, the Canadian Supreme Court gave priority to "the patient's right to know what risks are involved in undergoing or foregoing certain surgery or other treatment."[89]

Under British law, it is now clear that the physician is required to warn his or her patient of the risks inherent in the recommended treatment, a legal duty similar to that found in the doctrine of informed consent. How the law developed to this stage will be seen

later, but at the moment one should note that under English law the doctor's duty to disclose the risks is restricted in its scope. His or her duty is concerned with disclosure of 'real' risks only.[90]

In determining whether a particular risk is a real one, English courts have generally rejected the transatlantic test that what the doctor should disclose is determined and judged by what the reasonable patient would want to know. This rejection has been confirmed by the majority of the House of Lords in the case of Sidaway v. Board of Governors of Bethlem Royal and the Maudesley Hospital.[91] The test was criticised as being damaging to the doctor/patient relationship and as uncertain in its application.[92] Instead English courts adopted the 'reasonable doctor' test, i.e., what a reasonable doctor would disclose in similar circumstances.[93] Further consideration will be given to this issue in chapter four infra.

B-COMPREHENSION OF INFORMATION;

It is often argued that a patient can not be said to have made a rational decision as to whether to consent to the recommended treatment unless he or she understands the information that the doctor is legally required to make known to him or her.

But from the legal point of view no court has expressly held that the doctor's duty extends beyond merely disclosing relevant information to the patient. In accordance with what has been said, the United States Supreme Court mentioned as the meaning of "informed consent" merely "the giving of information to the patient as to just what would be done and as to its consequences"[94]

However, there is strong support in the common law for the existence of the requirement of understanding - that patients understand what the doctor is required to disclose in order to obtain

his or her patient's valid consent. In effect the common law establishes that legally effective consent can be given only by competent persons. Accordingly, a person who lacks the capacity to consent can not be said to have rendered a legally valid consent. In the medical context, however, the question which often arises is not about the patient's capacity to consent, since even a minor may be asked to render his or her consent for a given treatment, but rather about the patient's competency in fact to make medical decisions.

The patient's competency is usually determined on the basis of his or her ability to understand the information disclosed.[95] Thus, if a patient is legally competent i.e., has the capacity to consent, and has been provided with the necessary information, these facts do not render his or her decision about health care a rational one if he or she does not understand the explanation made available by the physician.[96]

It should be noted, however, that the possible inability of the patient to understand the information given by the doctor may result from the manner of communication (the vocabulary which is adopted), and/or from the condition of the patient (distress or confusion). For this reason physicians are usually asked to choose carefully the vocabulary they adopt in explaining their proposed therapies. It goes without saying that technical language will not ordinarily suffice to warn the patient about a risk inherent in the recommended treatment. As has been pointed out, "one can only communicate in terms which, based on experience and perceptions of the recipient's capacity, one believes he will understand".[97] In other words, the doctor should disclose information in such terms that as a reasonable man would believe the patient would understand.

Doctors may argue that certain information is so technical that

the non specialist patient is unlikely to grasp it. Such a claim, however, can amount to little more than a pretence for non disclosure, for as Buchanan[98] pointed out the doctor's legal duty to disclose information does not apply only when he or she reasonably believes that the patient will understand what he or she is informing him or her of. As he noted:

> "The doctor does not and can not have a duty to make sure that all the information he conveys is understood by those to whom he conveys it. His duty is to make a reasonable effort to be understood".[99]

Moreover, even if the patient does not understand the highly technical nature of the information, the disclosure "may nonetheless have an important symbolic [purpose] which may prove to be vital to the creation or maintenance of trust and respect between doctor and patient, and to the enhancing of the patient's autonomy."[100]

The problem of understanding is most likely to occur when dealing with patients from the special groups, namely, children, the mentally handicapped and the mentally ill. It is believed that these persons are unable to understand the explanation that might be made available to them. However, once again, it is argued that even if these patients can not understand the technicalities of a certain procedure, they can still comprehend the likely consequences of the treatment or its side effects if this information is made known to them in the simple and everyday language.[101]

CONSENT ELEMENTS

Mention was made before that for consent to be used as a defence by a doctor, this consent must be freely and voluntarily granted as well as competent.

C-VOLUNTARINESS;

In order to give a voluntary consent, the patient must be free as to whether to assent to the proposed treatment. He or she must be in a position to choose between consent and refusal without any feeling of constraint.[102] He or she must be physically and mentally able to consent voluntarily. In the Canadian case of Beausoleil v. Soeur de la charité[103], the court rejected the defence of consent since there was evidence that the patient's consent was obtained following the giving of a sedative. It was found that the patient consented in words of defeat, exhaustion and abandonment of willpower.

There are various factors which may render consent ineffective. Consent may be expressly given, but for one reason or another it won't be considered valid from the legal point of view. Generally speaking, consent can be invalidated by fraud, coercion or mistake.

(I)-Fraud;

The law is well settled that if the authorization for a therapeutic intervention is obtained through fraud, such consent is legally meaningless. Such fraud may consist in a misrepresentation of the character of the procedure or in a misrepresentation of the expected consequences of it. In Hobbs v. Kizer[104], the court held that the consent of the plaintiff for the supposed operation to remove a vaginal abcess, was fraudulently obtained, for the physician intended in fact to perform an abortion on his patient who has been made pregnant by his having illicit relations with her. A similar approach has been taken by an English court in the case of Regina v. Case[105], where the doctor had sexual intercourse with his fourteen year-old patient under the pretence that he was treating her suppressed menstruation. The examples mentioned above show that any

procedure undertaken following a fraudulently obtained consent can be tortious.

(II)-Coercion:

The law does not recognize an authorization given as a result of coercive measures. Accordingly, one can not compel a patient to undergo a course of treatment by means of threats or intimidation. In this respect, it was held in Heek v. City of Loveland[106] that where consent is obtained through coercion or duress that consent is ineffective since in fact the patient submits himself to the defendant's act against his desires. However, in the case of Ollet v. Pittsburgh,c.c and St.L.Ry.Co[107], the court reached a different conclusion. In this case the crew of a railroad train which had run over a boy injuring his foot, took him to a hospital despite his protests. It was held that this case is different from the previous one as a result of the fact that the patient involved is a minor who is incapable of consenting to or refusing such treatment. In addition, it was a case of emergency which made it unwise to wait until the boy's parents were notified.

(III)-Mistake:

When the doctor mistakenly renders a treatment or performs the treatment upon the wrong patient or in a manner different to that which was agreed upon between the parties, the submission of the patient to such actions or administration of treatment does not lead to an implied consent. An example of this arose in the case of Hershey v. Peake[108] where the court found for the plaintiff patient for the unauthorized extraction of certain teeth which had been proceeded with mistakenly by his dentist. Similarly, in Gill v. Selling[109], the

court held the physician liable for damages for the unauthorized performance of a lumbar puncture which was originally meant for another patient but was given by mistake to the plaintiff who merely visited the physician's office in order to obtain the results of a blood test.

Examples concerning the administration of treatment by mistake are in some ways similar to those involving the performance of further procedures whether related or unrelated to the original treatment for which consent was given. However, in the examples mentioned above, the element of intent is almost lacking, for had the doctor not been confused, he or she would have treated the right patient or proceeded with the right treatment.

D-COMPETENCY;

Generally, only competent persons are allowed to give or withhold consent to medical treatment. Accordingly, no problem arises when the consent or the authorization is warranted by a sane and legally competent patient.

However, the most complex problems relating to consent to medical treatment arise when the patient shows some incapacity which may prevent his or her consent from being meaningful. Examples involve patients from the special groups namely, children, the mentally ill and mentally handicapped persons. It is believed that these persons are unable to understand the nature and significance of their situations, and therefore they can not be said to have given valid consents. The principle is simply that one can not authorize the performance of a course of action of which he or she is rationally unaware.

However, it is often argued that the possible inability to

understand with respect to these people is a matter of degree, and the law should be flexible in determining whether the particular patient has the capacity to consent in accordance with his or her particular situation. For instance, due to the general lack of knowledge and experience of minors, the law has made special provisions for their protection. In relation to the capacity of a minor to consent to medical treatment, there is a tendency for courts to look towards the intellectual maturity of the patient rather towards his or her age.[110]

In a similar way, cases involving the mentally ill and mentally handicapped persons must be treated according to their own merit. No paternalistic interference can be permitted with these persons' decisions unless it is clear in their individual case, and in the case of the particular decision in question, that they are not capable of understanding the nature, the purpose and the likely effect of the proposed treatment and are not therefore capable of giving valid consents.

It is convenient to note in this respect that the legislation affecting this particular group, although affecting only those who are detained as a result of a serious mental illness, allows the imposition of certain treatment upon these patients but only with their consent.[111]

Section 97 of the Mental Health (Amendment) (Scotland) Act 1984 states expressly that, except in a case of emergency which requires immediate intervention, a detained patient shall not be given any form of treatment unless he or she has consented to it. Before the treatment is administered, however, a medical practitioner and two other persons appointed for this purpose must testify in writing that the patient is capable of understanding the nature, the purpose and

the likely effect of the proposed treatment and has consented to it. The appointed medical practitioner must further testify that the proposed treatment is necesssary to alleviate or prevent the deterioration of the patient's condition and that it should be administered.[112] Moreover, according to section 101, when it is appropriate to seek the patient's consent and it is obtained, with the exception of a case of emergency which requires immediate intervention, the patient can withdraw his or her acquiescence to further treatment at any time.

2:7 CONCLUSIONS:

The preceding sections have sought to demonstrate, through discussion of patients' rights, that the patient as human being has no less rights than does a healthy person, and that he or she must be treated as an autonomous person when he or she has the capacity to decide about his or her own future in respect of his or her health care.

It was argued that the patient has the right to consent to any medical intervention either in therapy or experimentation and that this right provides him or her with a sufficient protection for his or her autonomy or self-determination. But, in order that consent have this effect it must be based on a sufficient disclosure of information, since it is this element which plays a central and fundamental role both in his or her autonomy and in the morality of the medical enterprise.

The only situation in which medical treatment might be administered without consent is that of an emergency which demands immediate attention for the preservation of the patient's life, limb or health when the patient is not in a position to consent to or

refuse treatment.

It was also argued in this chapter that where it is appropriate to obtain consent, the physician is now legally asked to disclose to his or her patient the relevant information in order to permit him or her to make a rational decision about whether to consent to the recommended treatment. Such a requirement is both vital and fundamental to the patient, for, as was already argued, one can not legally consent to the invasion of one's own body if one is unaware of the nature and consequences of the invasion. The disclosure of information must be made in simple language in order to ensure that the patient understands it. It must also be free from any misrepresentation of facts or of the nature of the procedure, for such may invalidate the patient's consent if he or she does authorize the performance of a certain treatment under such circumstances. Different standards are used in determining the adequacy of information that is to be disclosed to the patient. Mention was made of the "professional standard" which is adopted by British courts, and the "reasonable or prudent patient" which appeared following the birth of the doctrine of informed consent in the U.S medical law.

It should be noted, however, that the doctor is not responsible for the possible inability of the patient to assimilate the information disclosed. It hard to reconcile this idea with the theory that the patient's consent must stem from knowledge and understanding. The fact that the patient can hardly comprehend the information, does not exonerate the doctor from his or her duty to disclose information. In such circumstances the physician is asked to make some effort to make himself or herself understood by the patient, for it is often argued that if the information is presented in everyday language it can be grasped by most patients.

The validity of the consent does not only depend on disclosure of information, it also depends on factors personal to the patient. This is concerned with patient competency and capacity to give a legally meaningful consent. This aspect of consent usually raises problems when dealing with persons from the special groups that include children, the mentally ill and mentally handicapped persons. It is submitted that the physician cannot legally approach the patient without his or her valid or informed consent if the latter has the legal capacity of granting it. It is noted, however, that the lack of capacity which may affect patients from special groups may justify the interference of other persons so that their consent is given by proxy. But when the capacity of the individual is not in doubt, he or she is the only person who can accept or reject the medical treatment based on a comprehensible and reasonable disclosure of information.

These are the general principles that govern consent to medical treatment. Before considering the the law of consent in the U.K, it will be necessary to outline the development of the doctrine of informed consent in the medical law of the United States, and that will be the task of the next chapter.

NOTES:

1-Campbell, A.V., Moral Dilemmas in Medicine, Edinburgh, Churchill Livingstone, 1984, p 94.

2-McLean, S.A.M., "The Right to Consent to Medical Treatment", in: Campbell, T. et al (eds), "Human Rights: From Rhetoric to Reality" Oxford, Blackwell, 1986. p 149.

3-Id.

4-Ibid p 150.

5-Id.

6-In the medical context interventions, and paticularly invasive one, are differently sanctioned than those under criminal law. The main reason could be that these interventions which may consist in injuries are carried out not for their own sake, but in order to prevent much more serious harms. See, Gordon, G.H, The Criminal Law of Scotland, Edinburgh, Green, (2 nd.ed), 1978, p 828.

7-McLean, S.A.M., loc.cit, p 150.

8-Ibid p 151.

9-Id.

10-Ibid 151-52.

11-See section four below, pp 49.

12-Namely, Mason, J.K. & Mc Call Smith, R.A., Law and Medical Ethics (2nd ed) London, Butterworths, 1987, p 141.

13-See McLean, S, and McKay, A.J., "Consent in Medical Treatment", in McLean, S.A.M., (ed) "Legal Issues in Medicine", Aldershot, Gower, 1981, p 97.

14-See Childress, J., "Who Should Decide?, New York Oxford, Oxford University Press, 1982, p 80.

15-Ibid, for discussion see Simmons, A.John, "Tacit Consent and Political Obligation", 5 Philosophy and Public Affairs. 274

(Spring 1976), see also Simmons, A.John, Moral Principles and political obligations, Princeton Guilford, P.U.P, 1979, pp 79.

16-Mclean, S.A.M., "Disclosure of information, Consent to Medical treatment and the Law", Ph.D Thesis, Glasgow University, 1987, p 62.

17-See Simmons (1979), op.cit, p 80.

18-See McLean and McKay, loc.cit, p 97.

19-See Mc Lean, S.A.M., (1986), loc.cit, p 156.

20-See Finch, J., Health Services Law, London, Sweet & Maxwell, 1981, p 245.

21-Re.D "A Minor", 1976 Family Div 185.

22-Hills V. Potter [1983] 3 All E.R 716.

23-Ibid p 717.

24-See Robertson, G., "Informed Consent to Medical Treatment" 97 L.Q.R 102 (1981) p 112-3.

25-Chatterton V. Gerson [1981] 1 All E.R 257.

26-United State v. Karl Brandl. Trials of war criminals before the Nuremberg Military Tribunals under control council law no 10 vol 1,2.

27-See, for further discussion infra chapter six, p 200-201.

28-See McLean, (1986), loc.cit, p 152

29-Marshall v. Curry [1933] 3 D.L.R 260.

30-Ibid at p 262.

31-The patient's refusal should also be based on information disclosure just as in the case of consent.

32-For further discussion, see Veatch, R.M., Death, dying and the biological revolution, New Haven, London, Yale University Press, 1986, p 116.

33-Natanson v. Kline 186 Kans 396, 354 P.2nd 670 [1960] at p 673.

34-Erickson v.Dilgard 44 Misc 2nd 27, 252 N.Y.S 2nd 705 (Sup.Ct 1962).

35-44 Misc. 2nd at p 31.

36-In re Estate of Brooks, 32 Ill 2nd 361, 205 N.E 2nd 435 (1965).

37-State v. Perricone, 37 N.J 463, 181 A 2nd 751 (1962).

38-In re Tuttendario 21, Pa Dist 561 (Quar.Sess.Phila.Co., 1911)

39-In re Hudson, 13 Wash. 2nd 673, 126 P.2nd 765 (1942).

40-In re Seiferth, 285 App.Div.221, 137 N.Y.S 2nd 35 (1955).

41-Downie, R.S., & Calman, K.C., Healthy Respect, London, Faber & Faber, 1987, p.232.

42-Williams, G., Textbook of criminal law, london, Stevens, 1978 p 531.

43-McLean, S.A.M., (Thesis), op.cit, p 69.

44-Id.

45-See R v. Eatch [1980] C.L.R. 651.

46-For further discussion, see Philip S.James, General Principles of the Law of Torts, London , Butterworths (2nd ed) 1964, pp 30, Watson, A.A, McLean, A.M., "Consent to treatment, a shield or a sword?" 25 Scott.Med.Jour. (1980) p 113, see also, McLean, S, and McKay, A.J., loc.cit, p 96.

47-See Walker, D.M., The Law of Delict in Scotland, Edinburgh, W.S, Green and Son, 1966, at p 351.

48-Childress, op.cit, p 78.

49-Kloss, Diana M., "Consent to medical treatment", 5 Med. Sci & the Law 89 (1965)

50-at p 97.

51-Childress, op.cit, p 78.

52-Mason, J.K. & Mc Call Smith, R.A., Law and Medical Ethics, (2nd.ed) London, Butterworths, 1987, p 141.

53-See p 36 above.

54-See Polson, C.J., The essentials of Forensic Medicine, Oxford, Pergamon Press, (2nd.ed.rev) 1965, p 533.

55-See Skegg, P.D.G., "Informed Consent to Medical Procedures" 15 Med.Sci. & the Law (1975) p 127.

56-See McLean and McKay, loc.cit, pp 96, see also Powell, R.F., "Consent to Operative procedures", 21 Maryland Law Review (1961), pp 192, see also Finch, J., op.cit, p 243.

57-See Polson, op.cit, p 537.

58-Devi v. West Midlands Regional Health Authority, 7 Current Law 44 (1980).

59-Roleter V. Stain, 39 Okla 572, 137 P.96 (1913).

60-Mulloy v. Hop Sang, 1 W.W.R 714 (Alta. A.D), [1935]

61-Where express consent is presented verbally, it is as effective as written consent. See Finch, op.cit, p 244.

62-Zaslow, J., "Informed Consent in Medical Practice", 22 The Practical Lawyer (1976) p 21, see also, Rozovsky, L.E., "Consent to Treatment", 11 Osgood Hall Law Jour (1973) p 113.

63-See Finch, op.cit, p 247, and Brazier, M., Medicine, Patients and the Law, Harmondsworth, Penguin Books, 1987, p 58.

64-See Calman, K.C., & Mc Lean, S.A.M., "Consent, Dissent, Cement". 29 Scottish Medical Journal (1984) p 211.

65-For further discussion, see Finch, op.cit, p 245 and Brazier, M., op.cit, p 57.

66-See Downie and Calman, op.cit, 236.

67-See Kennedy v. Lockwood [1932] 1 D.L.R 507, p 527.

68-See Skegg, P.D.G., Law Ethics and Medicine, Clarendon Paperbacks, 1988, p 88, Speller, S.R., "Law Relating to Hospitals and Kindred Institutions", (5th ed) London, H.K Lewis, 1971, p 109. See also, Wayne, D.L., "Informed consent as a theory of medical

liability" (1970) Wisconsin Law Review p 889.

69-Halushka v. University of Saskatchewan, [1966] 53 D.L.R 2nd 436, see also, chapter six infra.

70-The development of the doctor's legal duty to disclose information will be considered when analysing the evolution of the doctrine of informed consent in the U.S.A. in infra chapter three.

71-See Applbaum, P.S., Lidz, C.W. & Meisel, A., Informed Consent, Oxford University Press, 1987, p 50.

72-For more discussion see Mason and Mc Call Smith, op.cit, p 152, see also, Landsverk, W.D., "Informed Consent as a Theory of Medical Liaility", Wisconsin Law Review 879 (1970), p 891.

73-See Poulin v. Zartman, 542 P.2nd 251, 275 n.57 (Alaska 1975).

74-See Flat Rev. Stat. Ann, 768, 47(3) a (2) West Cum Supp (1979).

75-Haw. Rev. Stat, 671-3 (b) 1976.

76-Utah Code Ann, 78,14-15 (1) (b) 1977.

77-Chatterton V. Gerson [1981] 1 All E.R P 257.

78-See Applbaum, Lidz, and Meisel, op.cit, p 152.

79-See Mason and Mc Call Smith, op.cit, p 152.

80-See Waltz, J.R., & Sheuneman, T.W., "Informed Consent to Therapy" 64 Northwestern University Law Review (1969) p 642.

81-Buchanan, A., "Medical Paternalism" 7 Philosophy and Public Affairs (1978) at p 377.

82-See Applbaum, Lidz and Meisel, op.cit, p 55.

83-Ibid p 57.

84-Meisel, C and Karnick, L.D, "Informed Consent to Medical Treatment" 41 University of Pittsburgh Law Review (1980) p 421.

85-Natanson V. Kline 350 P 2nd 1093 (Kans 1961).

86-Canterbury v. Spence 464 F 2nd 772 (D.C Cir 1972).

87-Ibid p 787.

88-For discussion see Applbaum, Lidz, and Meisel, op.cit, p 41, see also Meisel and Karnick, loc.cit, p 421.

89-Reibl v. Hughes [1980] 114 D.L.R (3rd) 1.

90-Chatterton v. Gerson [1981] 1 All E.R p 257.

91-Sidaway v. Broad of Governors of Bethlem Royal and Ors [1985] 2 W.L.R 480.

92-See Brazier, op.cit, p 66, see also her article, "Patient autonomy and consent to treatment, the role of the law ?" 7 Legal Studies(1987) p 182.

93-See Robertson, G., "Informed Consent to Medical Treatment" 97 Law Quarterly Review (1981) p 102.

94-Planned Parenthood v. Danforth, 428 U.S 52,67 N8 (1968).

95-See, Meisel, C., and Roth, L.M., "Toward an informed discussion of informed consent" 25 Arizona Law Review (1983) p 286.

96-See Applbaum, Lidz and Meisel, op.cit, p 60.

97-Waltz, and Scheuneman, op.cit, p 644.

98-Buchanan, A., loc.cit, p 386

99-Id.

100-McLean, S, "The Right to Consent to Medical Treatment", supra.cit, p 162.

101-Ibid p 163

102-See for example, Bowater v. Rowley Regis Corporation, [1944] K.B.476, where Scott L.J said;

> ".... a man can not be said to be truly willing unless he is in a position to choose freely, and freedom of choice precludes not only knowledge of the circumstances on which the exercise of choice is conditioned so that he may be able to choose wisely, but the absence from his mind of any feeling of constraint so that nothing shall interfere with the freedom of his will". at p 479.

103-Beausoleil V. Soeur de charite (1964), 53 D.L.R 2d 65, [1965] Q.B,

104-Hobbs v. Kizer, 236 F. 681 (8th Cir 1916).

105-Regina v. Case , 1 Eng . L and Eq . Rep 544 (1850).

106-Meek v. City of Loveland, 85 Colo 346 (1929).

107-Ollet v. Pittsburgh 201 Pa 361, 50 A. 1011 (1902).

108-Hearshley v. Peake, 115 Kan.562, 223 P. 1113 (1924).

109-Gill v. Selling, 125 Or.587, 267 P.812 (1928).

110-Gillick v. Norfolk and Wisbech Area Health Authority, [1984] Q.B 581, [1984]1 All.E.R 365, [1986]A.C 122, [1985] 1 All.E.R 533, CA Revsd [1986] AC 112, [1985] 3 All.E.R 402, H.L.

111-See, Mental Health (Amendment) Act. 1983, Mental Health (Amendment) (Scotland) Act. 1984, Part. X.

112-Mental Health (Amendment) (Scotland) Act. 1984, Section 97.(2) (b).

CHAPTER THREE

THE EVOLUTION OF THE DOCTRINE OF INFORMED CONSENT IN THE U.S.A

The legal theory of valid consent as applied nowadays in the medical context is the result of the developments that took place in the law of consent during the last few decades. In effect, the legal requirement of providing consent developed from a mere authorization to invade one's own bodily integrity to a legal means to protect the patient's right to autonomy and self-determination, and to enhance rational decision-making in medicine as well as in the doctor-patient relationship.[1] Analyzing how the law developed to this stage is the task of this chapter. This historical analysis shows that the evolution of the transatlantic doctrine of informed consent is important for comprehending the contemporary notion of valid consent[2] under the British legal systems.

Before discussing the major circumstances in which the doctrine of informed consent emerged, it is convenient to start first by defining the term 'informed consent'.

Originally, the notion of informed consent derives from a recognition of the patient's right to self-determination which is "the most humane principle advanced by the post-theistic West"[3]. In effect, informed consent is connected to the principle of autonomy. The clearest early enunciation of the principle of autonomy in the area of medicine can be found in the phrase of Justice Cardozo:

> "The root premise is the concept, fundamental in American jurisprudence, that every human being of adult years and sound mind has a right to determine

what shall be done with his own body"[4]

The doctrine suggests that the physician is required to provide his or her patient with sufficient information as regards the proposed therapy so as to give the patient the opportunity of making an informed and rational[5] decision as to whether to submit to the treatment. As will be seen below the doctrine of informed consent is a legal concept that imposes on the physician two separate but related duties; the duty to disclose to his or her patient, in addition to the nature of the proposed therapy, the risks inherent therein as well as existing alternative treatments, and a subsequent duty to obtain the patient's consent before administering treatment[6]. Failure to disclose this information and to seek consent may result in an action based on non-consensual treatment if the patient does not understand what he or she is exposing his or her bodily integrity to.

The starting point of this discussion will be to look at the value given to the patient's desires and decisions in health care in the Nineteenth and early Twentieth centuries.

3:1 CONSENT AND MEDICAL PRACTICE BEFORE THE TWENTIETH CENTURY:

By and large, this period witnessed a rapid expansion in medicine. It is also characterized by physicians' preoccupation with professional standards of care and their resistance to medical "quackery".

There is some evidence that consent-seeking practices existed during the period in question, especially to consequential interventions such as surgery. The legal requirement was that physicians should obtain their patients' authorization prior to any administration of treatment.

One of the earliest reported cases to have applied this rule was the late eighteenth-century English case of Slater v. Baker & Stapleton[7]. The case was concerned with an action for breach of contract. In effect the plaintiff consulted his physicians Drs Baker & Stapleton for the removal of bandages from a partially healed leg fracture. Contrary to the agreement made between the parties, the hired physicians refractured the leg "ignorantly and unskillfully", said the plaintiff, and over his express protests. Then the physicians placed the leg in an apparently new apparatus that was still under experimentation, designed to stretch and straighten the leg during the rehealing. Expert testimony evidenced that the use of such equipment was contrary to standard practice, as was refracturing a leg unless the bone was not setting properly. Moreover, even if such procedure were carried out, it should not be done without the consent of the patient concerned. During the trial the defendants maintained that because the plaintiff complained of an unauthorized refracture over his objections, his action should have been brought in trespass. In order not to dismiss the plaintiff's action because it was brought under an inappropriate 'writ', the court held the physicians liable under contract theory. The court decision in this case constituted a recognition of the ethical and legal requirements of consent. The court also mentioned the importance of communication in the doctor/patient relationship. The court made the remark that it is customary for the surgeon to seek his or her patient's consent and observed that;

> "...it is reasonable that the patient should be told what is about to be done to him that he may take courage and put himself in such a situation as to enable him to undergo the operation."[8]

In another case in the nineteenth century the issue of consent to treatment was faced head on. That was in Wells v. World Dispensary Medical Association[9]. The case involved a claim on the part of the plaintiff patient that the defendant physicians had falsely and fraudulently obtained her consent for the removal of an alleged uterine tumor. At the outset the plaintiff's counsel failed to prove that no tumor existed at the time of the operation. He subsequently attempted an alternative argument in malpractice which was upheld by the court. The court held that the defendants were negligent not for fraudulently seeking the patient's consent, but for removing the tumor.

Pernick[10],in his study of the "behavioral values that were transmitted through the example of daily medical practice"[11], shows that patients' desires and decisions in health care were recognized and that patients' refusals to submit to treatments were also respected.[12] Pernick comes to the conclusion that the patient could even prevent a procedure which is as important and fundamental as a life saving one.[13]

The early cases reported in the Boston Medical and Surgical Journal show, however, that "the style of handling problems of consent was not fixed or routine"[14]. But doctors did not totally ignore patients' opinions regarding the proposed treatment and at the same time they did not appear "to proceed in accordance with any established formal or informal practices of informing or obtaining consent"[15]. On the other hand other cases confirm the conclusion reached by Pernick that physicians sometimes respected their patients' decisions not to proceed with the proposed treatment.

A better example of soliciting consent, as opposed to merely

respecting patients'refusals, is found in the case reported in the Boston Medical and Surgical Journal[16], in which a hydrocephalic baby, whose head circumference had continuously increased in size since birth, needed an operation. The surgeon proposed to the parents to operate on the baby, but he could not obtain their consent without assuring them that a better state of health would follow the performance of the operation in question. Another illustration of consent seeking, evidencing both purposeful disclosure of information and an invitation to autonomous choice by the patient is found in the case of a woman with polypous disease of the vagina[17]. The surgeon informed the patient that the source of her troubles lay in a diseased structure in the vagina, and that the only possible remedy would be the surgical removal of the diseased part. The patient preferred another course of treatment although it was not as efficient as the one proposed by the treating physician. The alternative treatment consisted in applying astringent and stimulating applications to the part affected.

Although the cases mentioned above give some evidence that at least some consideration was given to consent-soliciting, it is difficult to identify the perceived justifications for these practices. One can not assert with certainty whether the patient's choice was respected for the sake of autonomy, or because disclosure provided some medical benefit for the patient, or because the proposed intervention required the patient's active cooperation, or because disclosure was commonly practised or consent legally required.[18]. As Faden and Beauchamp observed, respect for autonomy is unlikely to be included as a justification for such practices because of the beneficence model which characterized medical practice in this period.[19] The first decision, as will be seen below, to have

expressly used the term self-determination was the early twentieth century battery case of *Schloendorff*[20].

3:2 CONSENT IN THE EARLY TWENTIETH CENTURY:

By the beginning of the twentieth century the medical profession knew another dimension. As the success of scientific knowledge in medicine began to increase, case reports and commentaries took on a more technical character, neglecting thereby to report information about doctor/patient interactions and consent practices. The increasing number of malpractice lawsuits also characterized this period. An article in the New England Journal of Medicine noted that legal action was undertaken by some unsatisfied patient once in every four days, soliciting legal redress for alleged malpractice[21]. This marked the beginning of doctors' confrontation of the "malpractice crisis".

In an attempt to redress the situation and to discourage lawsuits the medical profession tried to rely on consent-seeking and communication with patients before the administration of treatment. Physicians were asked to obtain their patients' consent prior to any administration of treatment and particularly in major interventions that need the use of anaesthesia[22]. Physicians were also urged to seek consent when, in the course of a given intervention, they discovered a new condition not anticipated before the operation, unless, if not treated, it would endanger the patient's life or health, in which case the doctor must treat the newly discovered condition with the implied consent of the patient.[23]

In addition to the use of consent-seeking practices in striving to avoid malpractice suits, the medical profession also relied upon the possibility of legal liability for failure to seek the patient's

consent. In this respect the Boston Journal reported an example of the legal dilemma of whether consent should be treated as one ordinary issue of medical custom or as authorizing what would otherwise lead to an action for assault and battery[24]. The report discussed the case of a physician involved in an allegation for non-consensual treatment: Delaware v. Gale.[25] The case consisted in an action brought by a woman against her male accoucheur for assisting her during delivery. At the time male assistance during labour was not a common practice, in fact it was regarded as improper. The woman testified that the defendant physician touched her body several times without seeking her consent and despite her express objections. The court held, after hearing the testimony of several doctors called for the defence, that the defendant physician's behaviour was appropriate and that he only performed his professional duty. The doctor was then discharged from criminal custody.

Generally, the early twentieth century cases were very often dealt with on the basis of negligence, but once "the nature and the scope of the patient's authorization is established, extension beyond it is a technical battery"[26]. To go ahead with the treatment without the patient's consent is considered as a pure instance of battery.[27] As was observed, these early cases "examined the principles underlying the physician/patient relationship, and applied that understanding to develop and illuminate the nature and scope of consent."[28]

The period between 1905 and 1914 saw four battery decisions considered as the first to have formulated the basic features of the doctrine of informed consent in the U.S.[29]These were; Mohr v. Williams [30]Pratt v. Davis[31], Rolater v. Stain[32], and the most often cited case of Schloendorff v. Society of N.Y Hospitals [33]

which was the first decision to have pioneered the use of the right of autonomy as a justification for the legal requirement of consent.

A-THE PRE-SCHLOENDORFF CASES:

Mohr v. Williams[34], Anna Mohr, the plaintiff patient, suffering from pain in her right ear, consulted her doctor who obtained her consent to operate thereon. During the operation the physician examined her left ear and realized that it was in a worse condition than the one he was about to treat. For this reason he operated on the left ear rather on the one he was hired and authorized to treat. Following the operation the patient's hearing in her left ear became further impaired. Consequently, she sued her surgeon on the basis of a battery action for the performance of the operation without her consent.

In deciding in favour of the patient, the court held that the physician should have sought the patient's authorization before treating the left ear. In this respect the court said:

> "The free citizen's first and greatest right, which underlies all others (the right to himself) is the subject of universal acquiescence, and this right necessarily forbids a physician or surgeon, however skillful or eminent, who has been asked to examine, diagnose, advise and prescribe, to violate without the permission the bodily integrity of his patient by a major or capital operation, placing him under an anesthetic for that purpose, and operating on him without his consent or knowledge"[35].

The message of the court seems to suggest that the patient's submission to a mere medical examination does not in itself give the physician *carte blanche* to go ahead with whatever he or she would think will benefit the patient's health or condition. The patient's

consent can not be implied from the mere fact that he or she seeks treatment. Exceptionally, the patient's consent may be obtained impliedly in the case of an emergency or when the surgeon discovers a new condition not anticipated in the course of the operation consented to. In such circumstances, it is practically impossible to obtain the patient's express consent, and to postpone the treatment until the patient's consent is sought may be fatal to the patient's health or life. Operating on the left ear of the patient, held the court, was not within the field of the operation consented to, and no case of emergency or of any other exception to the rule of seeking consent occurred.

The court insisted that the scope of the consent should be respected. In this respect the court noted that when the physician solicits the patient's consent and the latter agrees to a certain course of action "...the patient thereby, in effect, enters into a contract authorizing the physician to operate to the extent of the consent given, but no further"[36]. As was remarked by some writers[37], nowhere did the court in *Mohr* use words like "self-determination" or "autonomy". However, the court used "the free citizen's...right to himself" and this has the same effect as the language of the right of autonomy or sef-determination. Moreover, by stating "If a physician advises a patient to submit to a particular operation and the patient weighs the dangers and risks incident to its performance, and finally consents"[38], the court treated consent as a "full decisional process and not merely as a bare permission to touch"[39].

Pratt v. Davis.[40]

In this case the patient was the subject of a hysterectomy without her consent. In the first instance the lower court could not find any English or American court decision that held a physician liable for the administration of treatment without the patient's consent, nor any that stated that consent-seeking was not required for the proper practice of medicine, but the early cases mentioned the possibility of implied consent.[41] The physician's counsel argued that the hiring of a doctor implies that he or she is authorized to do whatever he or she would think is necessary or beneficial to the patient's condition.[42] But the lower court rejected this argument and held the physician liable for battery.

Just after the decision in *Mohr* in 1906, the *Pratt* case reached the Illinios Supreme Court which upheld the decision of the lower court. The Supreme Court made it clear that implied consent is to be relied upon only in emergency circumstances, or when the surgeon discovers a new condition, not anticipated before the operation, that requires immediate treatment. The latter decision constituted an influential precedent for later cases in other states' courts.

Historically, the *Mohr* and *Pratt* decisions are important for reminding doctors to seek their patients' consent prior to any touching or intervention and for having limited the use of implied consent to emergency circumstances, as well as for their use of strong language as regards autonomy in health care decision-making.

Rolater v. Strain [43]

In this case the plaintiff consulted her physician for the drainage of an infection in her foot. She expressly instructed the physician not to remove any bone from her foot. In the course of the

operation, the surgeon discovered that the sesamoid bone was in an unusual position which blocked access to the joint which was to be drained, so the surgeon removed it. There was some evidence that the bone has no purposeful function and the operation would not have been successful without removing the bone. The defendant argued that, to the contrary of the *Mohr* and *Pratt* cases, his patient had in fact consented to the operation and that it was performed on the correct foot. In holding the physician liable for battery, the court said that the operation was not performed in accordance with the manner agreed upon between the parties and consented to.

Mohr had suggested, as seen above, that some procedures not consented to might enter the scope of the consent already obtained. *Rolater*, however, held that when the patient limits the extent of his or her consent, this limitation "expressly forbade, against the physician's professional judgment, a procedure within the operative field".[44]

B-THE SCHLOENDORFF CASE.

Schloendorff v. Society of N.Y Hospitals[45]. The plaintiff entered the hospital for the purpose of an abdominal examination under anaesthesia. She instructed the physician that no operation was to take place should any need for intervention be discovered during the examination. When she was under ether, the surgeon removed a fibroid tumor from her abdomen. Ironically, a verdict was sustained for the defendants by the court of appeals because no master-servant relationship existed between the hospital and the doctors that performed the operation. The court could neither find any violation of consent nor mentioned anything about the information that the patient needs to exercise his or her right of self-determination. Moreover,

the court encountered the argument that the patient had waived any claim for negligence by attending a charitable institution. In this respect the court held that the operation was trespass and no waiver could be found in the commission of an illegal act. Judge Cardozo stated that it was a trespass:

> "Every human being of adult year and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable for damages."[46]

Cardozo's formulation reminded physicians that the patient has a right to protect his or her bodily integrity by choosing whether he or she is to be treated medically, in what way and the extent of the treatment. Any inattention to this right may expose the physician to an allegation of battery for his or her unauthorized invasion of the bodily integrity of the patient, no matter how skilful, faithful or beneficient is the physician when approaching the patient.

The decision also recognized that when an emergency occurs and it is necessary, as opposed to merely convenient, to operate on an unconscious patient before consent can be obtained, the surgeon can administer the treatment without the patient's consent. But in this case the court found that no emergency existed. In fact, prior to the operation, the patient had already prohibited the performance of any intervention should any condition be discovered during the examination. The fact that the surgeon discovered the tumor which could have endangered the life of the patient could not imply a consent if one considers the earlier express prohibition, even though, as mentioned before, good medical practice might have urged an immediate intervention.

Soon afterwards, *Shloendorff* became the most cited case in later decisions, as some scholars noted[47]. Several reasons can be postulated for its popularity: Judge Cardozo, already famously known, pioneered the use of the term "self-determination" which is in itself a "catch phrase"[48]. In addition, the decision came from the New York court, so influential that other courts were already ready to follow such an important and distinguished precedent.

In this way *Schloendorff* and the other cases formulated the battery theory based on respect for the patient's right to self-determination. These early cases, in particular *Mohr,* evidenced a real consideration of the role of the patient in health care decision-making, especially his or her right "to weigh dangers and risks" before authorizing any course of treatment. Following the *Schloendorff* decision, battery theory continued to be applied in some other courts as a basis of liability[49]. In other jurisdictions, however, the consent issue was dealt with as a matter of malpractice.

In general, what can be safely be said about the law of consent in the early twentieth century is that "a more complicated set of rules began to develop beyond the original simple proposition that a physician might not treat a patient without the patient's authorization"[50]. One of these early rules about consent-seeking is that the physician is not only responsible for obtaining his or her patient's consent, but that he or she should also not misrepresent the nature of the procedure and the expected consequences, for such conduct may invalidate the patient's consent and expose the doctor to an action for non-consensual treatment[51]. Courts generally indicated that fraudulent, deceptive or misleading information invalidated the patient's consent. Although no legal rule existed at the time that imposed a duty upon the physician to disclose information, in

particular information relating to the risks inherent in the proposed therapy and its consequences, courts made it clear that if such disclosure takes place it must be truthful. This early rule constituted "the seeds of the requirement of an affirmative duty of disclosure"[52].

3:3 THE TRANSITION FROM SIMPLE TO INFORMED CONSENT:

No significant development was noted during the four decades that followed the decision in *Schloendorff*. As noted before, different courts treated consent issues either in battery or in malpractice. However, a group of cases in the late 1950s and early 1960s marked a major development in the law of consent: a transition from the traditional duty to obtain consent into an explicit duty to disclose certain forms of information. These constituted the first contemporary "informed consent" cases. "Informed" was the new term added to consent in the landmark decision of Salgo v. Leland Stanford Jr Booard of Trustees in 1957.[53]

A-THE SALGO CASE:

The case involved a permanent paralysis that was suffered following an aortography procedure performed upon the plaintiff at Stanford University Hospital. The patient brought an action against his physicians alleging that the latter were negligent in its performance as well as in failing to warn him of the risk of paralysis: The court's view of the law on the subject was stated thus:

> "A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed

> treatment. Likewise the physician may not minimize the known dangers of a procedure or operation in order to induce his patient's consent. At the same time, the physician must place the welfare of his patient above all else and this very fact places him in a position in which he sometimes must choose between two alternative courses of action. One is to explain to the patient every risk attendant upon any surgical procedure or operation no matter how remote; this may well result in alarming the patient who is already unduly apprehensive and who may as a result refuse to undertake surgery in which there is in fact minimal risk, it may also result in actually increasing the risks by reason of the psychological results of the apprehension itself. The other is to recognize that each patient presents a separate problem, the patient's mental and emotional condition is important and in certain cases may be crucial and that in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent."[54]

It is obvious that the California court imposed liability on the physician if he or she failed to disclose any facts that were necessary for the patient to render an intelligent decision as to whether to consent to the proposed therapy. The physician is allowed, however, "a certain amount of discretion"[55]. Although "it is rather difficult to determine what is a certain amount of discretion"[56]as Myers observed, the statement in *Salgo* is very often referred to by other courts. In *Salgo*, two factors were cited as a justification for the physician's discretion; namely the patient's mental and emotional condition. After *Salgo*, the majority of juridictions adopted the same language to justify limitation of the duty of disclosure.[57]

Salgo also brought new elements into the law;

1-The new duty to inform the patient about risks attendant on therapy and the possible alternative treatments, which is an extension of the already settled duty to inform about the nature and consequences of the proposed therapy.

2-Unlike earlier court decisions the court in *Salgo* considered, not merely whether a consent had been rendered to the proposed therapies, but whether it had been informed, i.e., preceded by information disclosure.

With the new facts of the case, and by "invoking the same right of self-determination"[58], the court in *Salgo* created informed consent as a legal requirement for proper medical practice. In other words the theory of informed consent is the result of the new factual situation and the application of the same theory of consent that had been applied to the early cases referred to. In this way, all consent issues, namely the nature, consequences, risks, benefits and alternatives formed the new set of information that patients need in order to reach an "intelligent" decision as to whether to consent to the proposed therapy.

It should be noted that *Salgo* had "tempered its extension of traditional battery analysis"[59] by allowing physicians to use "a certain amount of discretion" in respect of the disclosure of facts that are necessary to reach an informed decision. The court, however, did not provide physicians with any guidance in relation to the use of that discretion.[60] Moreover, although the *Salgo* court cited battery cases, including *Schloendorff*, in support of the duty to disclose, there is still a confusion as to whether the court based informed consent in battery or in negligence[61]. The court itself did not discuss the issue. In this respect, it is convenient to invoke the work of Professor McCoid who had already suggested a choice between

battery and negligence theories a few months before the *Salgo* case was decided[62]. In effect, in his 1957 article, McCoid, studied the courts' decisions in all previous cases that involved the administration of treatment without authorization in order to determine whether there was any distinction between negligent, malpractice, and non-consensual treatment, or whether courts applied the same standard of conduct in all cases concerned with physicians' deviations. Because the failure to seek consent and negligent treatment are both considered improper actions on the part of doctors, McCoid suggested that battery and assault analysis should be confined to those relatively few cases in which the physician has engaged in intentional deviations from routine and accepted practice. Other cases ought to be tried on the basis of other principles. He suggested that there should be a single basis of liability in all malpractice cases;

> "The basis of liability should be deviation from the standard of conduct of a reasonable and prudent doctor of the same school of practice as the defendant under similar circumstances. The author believes that under such a standard the patient will be properly protected by the medical profession's own recognition of its obligation to maintain its standards. One particular obligation which the law may properly exact or impose, however, is the obligation of a doctor to make a reasonable disclosure to the patient....and then permit the patient to decide whether to submit to the treatment or not. To overcome any difficulties of proof, the law may also properly create a presumption that where the patient has not given his express consent to the operation or treatment, there has been a deviation from the standard of proper medical care, which presumption will impose upon the doctor the onus of coming forward with justification of his conduct by the use of qualified medical testimony."[63]

McCoid also argued that even if the physician is involved in a

case where all the requirements of the application of the battery theory are met, the physician merits special treatment because he or she usually performs his or her professional duty in good faith and for the benefit of the patient.[64]

After the *Salgo* decision, informed consent cases that applied the battery theory demonstrated an ability equal to that of negligence theory "to address difficult and important consent issues"[65]. However, most courts began to recognize the inappropriateness of battery theory as a basis of liability and suggested that it should be rarely applied. The shift in law towards negligence analysis took place few years later, a shift that was, to some extent, orientated by McCoid's influential thoughts on the issue, as noted by most commentators.[66]

B-BATTERY CASES AFTER SALGO:

Gray v. Grunnagle:[67] In this case the patient authorized what he was told was an "exploratory operation". He understood that to be a simple incision that would be made in his spinal column solely for the purpose of diagnosis, and that no attempt would be made to treat the condition he was suffering from once the diagnosis was complete, at least until he was advised of its nature and asked to consent to it. For the doctors, however, the operation meant more than that. For them, once the source of the trouble was identified, every effort would be made to treat or correct the pathology, or alleviate the symptoms. During the procedure an attempted corrective treatment had been performed, but unfortunately resulted in paralysis. The patient based his action both on medical negligence and on treatment without authorization, claiming that his consent had not been informed and in particular that he had not been warned of the risk of the paralysis

that materialized. Despite the verdict of the jury who awarded $80.000 for the plaintiff, the lower court gave judgment for the defendant. This decision was reversed on appeal and judgment entered on the verdict. The appellate court held that although there was no evidence that the procedure had been performed negligently, it had been done without the patient's informed consent, because the latter did not in fact understand the terminology used when physicians sought his consent, regardless of the written consent he had given when entering the hospital.

Berkey v. Anderson:[68]

This case connected the duty of disclosure to the law of fraud and deceit. In *Berkey*, the patient consented to a procedure called "Myelogram", without any warning of the risks it involved. The patient testified that prior to the procedure he asked his doctor whether the myelogram would be similar in nature to the electro-myograms he had already undergone. The physician answered that this procedure was simply a diagnostic and exploratory one and that the most uncomfortable thing about it would be being tilted about on a cold table. Following the procedure, the patient suffered several injuries in the spinal column. He subsequently sued his doctor alleging that the latter had misrepresented to him the real nature of the procedure by not having warned him that the procedure also involved a spinal puncture. After having reviewed the information provided by the physician, the court found that the patient's consent was in fact uninformed and therefore invalid due to the inadequacy of the physician's explanation of the nature of the procedure. The court held that on the facts the jury could have concluded that the reassuring language of the physician "was actually deceptive"[69].

The court also focussed on the physician- patient relationship as fiduciary in character, and indicated that this very character imposes on the physician a duty of full disclosure of facts. The main question before the court was whether the patient received sufficient information as regards the nature of the myelogram so that he could reach an intelligent or rational decision as to whether to consent to the treatment.[70] Therefore, like *Salgo,* the court applied a patient-centered disclosure standard. It also introduced the element of deception, as did some of the early cases[71] to invalidate the plaintiff's consent.

Cooper v. Roberts:[72]

The plaintiff in this case, as in previous cases, had not been fully informed of the risks inherent in the proposed procedure. In this case the physician failed to warn the patient of the risk of stomach puncture during the performance of a diagnostic examination done by a fiberoptic gastroscope. By using almost the same language and reasoning of the precedent battery cases the court in *Cooper* said that informed consent's first interest is to "[have] the patient informed of all the material facts from which he can make an intelligent choice as to his course of treatment, regardless of whether he, in fact, chooses rationally"[73]. In determining the scope of information disclosure that is needed to ensure an informed consent, contrary to negligence cases that applied the professional standard, the court in *Cooper* opted for the reasonable person standard. In this respect, the court argued that the latter standard is more appropriate to keep the balance between the patient autonomy and "the interests of fostering the practice of responsive, progressive medicine."[74]

These battery cases including *Salgo* followed, to some extent, the early twentieth century cases in terms of reasoning and justification. However, these cases faced much more complex problems, in particular the problem of determining the risks that should be disclosed, a problem that was first identified in *Salgo*. It does not necessary follow that earlier cases ignored these problems, it only means that "the courts had not heretofore needed to respond to them on the facts before them"[75].

As noted before, some courts continued to ground informed consent on battery theory, others however, probably influenced by McCoid[76], were coming to deal with the issue according to the law of negligence. The first court to have applied negligence theory in informed consent cases is the Kansas Supreme Court in Natanson v. Kline.[77]

3:4 NATANSON AND THE SHIFT TO NEGLIGENCE:

Natanson v. Kline.[78] Following a successful operation for the removal of breast cancer, plaintiff Natanson consented to a precautionary cobalt radiation treatment. Despite all normal precautions that the defendant radiologist observed during the administration of the treatment, the patient suffered serious injuries which consisted in the destruction of skin, tissue and bone in her chest area. She brought an action in malpractice claiming that the defendant physician had been negligent in failing to inform her that the treatment involved substantial risk of harm even if performed with due care. Her physicians recognized that although she authorized the performance of the therapy, she had not received an adequate explanation about the inherent risks of the procedure. The court held;

1-Before the administration of any treatment that involves substantial risk of injury, where no emergency occurs, the physician

has a legal duty to inform his or her patient of such risks. In expressing the duty of disclosure and its connection to the patient's right to self-determination, the court used the same strong language familiar to the early battery cases including *Schloendorff;*

> "Anglo-American law starts with the premise of thorough-going self-determination. It follows that each man is considered to be the master of his own body, and he may if he is of sound mind, expressly prohibit the performance of life-saving surgery, or other medical treatment. A doctor might well believe that an operation or form of treatment is desirable or necessary but the law does not permit him to substitute his own judgment for that of the patient by any form or artifice or deception."[79].

Like precedent courts,e.g *Salgo*[80] and *Mohr*[81], *Natanson* emphasized information disclosure as a fundamental element for rational decision-making, stating that it was the doctor's duty to inform the patient about all facts necessary for an intelligent decision as to whether to consent to the proposed therapy. The court also followed precedent cases in the use of the principle of self-determination as a justification for requiring the patient's informed consent.

2-Contrary to previous informed consent cases, *Natanson* applied negligence analysis as the basis for liability arising from the failure to disclose information. In this respect the court stated that when the physician violates his or her duty of information disclosure, he or she is liable in negligence even if he or she performs his or her professional duty with due skill and care.

The court found that the physician made no disclosure of facts, therefore "he failed in his legal duty to make a reasonable disclosure to the appellant who is his patient as a matter of law"[82].

Moreover, the court said that even if the physician informed his patient about some facts in relation to the treatment that had been performed, other issues would have arisen, in particular whether the disclosed information had been sufficient for the patient to make an intelligent decision. The court said:

> "The expert testimony of a medical witness is required to establish whether such disclosures are in accordance with those which a reasonable medical practitioner would make under the same or similar circumstances."[83]

Natanson, therefore, considered the question of what risks ought to be disclosed to be a matter of medical judgment. In determining whether the physician fulfilled his or her duty to make a reasonable disclosure of inherent risks, the court adopted the "reasonable" or "prudent" doctor test,i.e did the defendant doctor disclose to his patient what a reasonable doctor would have disclosed in similar circumstances. Accordingly, depending on the circumstances, a physician's failure to disclose certain facts may be justified, if expert testimony evidences that the physician's silence is in accordance with reasonable medical practice. But in the case before the court, there had been no disclosure at all as the patient's physicians recognized. So the patient was not required to prove by expert testimony that the doctor had been negligent. Instead, the burden of proof was shifted to the doctor to give evidence that his failure to disclose had been reasonable in the circumstances. The court continued; "[to] hold otherwise would be a failure of the court to perform its solemn duty."[84]

The application of the law of negligence in informed consent cases introduced some new elements. In negligence theory the patient's

consent does not exonerate the physician from liability even if he or she performs his or her legal duty as skilfully as any of his or her peers will. The treatment can be administered perfectly, but if a risk inherent in the therapy that was not warned of materializes the physician may be liable.

The application of negligence theory also requires that a link be made between the doctor's failure to inform about inherent risks and the patient's decision to undergo the treatment. This is known as the requirement of causation. Some writers refer to it as the "causation-decision".[85] In order to succeed in a claim in negligence the patient has to prove that he or she would not have consented to the treatment, and thereby suffered injury, had he or she been warned of the risks. In *Natanson*, the court held that when the patient appreciates the danger involved in the proposed therapy, the failure of the physician in his or her duty to make a reasonable disclosure to the patient "would have no causal relation to the injury"[86]. The subjective test applied in *Natanson*, however, may subject the physician to the danger of the patient's bitterness and disillusionment for it would be surprising, as the court said in Cobbs v. Grant[87], if the unsatisfied patient did not claim that had he or she been informed of the risks of the procedure he or she would not have submitted to the treatment.

It is worth noting that the application of negligence theory, with its fundamental requirement of establishing the link between the injury suffered and the physicain's failure to disclose information about the inherent risks, may limit the patient's recovery of damages when the court is doubtful about whether the patient would not have consented to the treatment if he or she had been informed about the risks. Hence, in negligence, if the fulfillment of the duty (in this

case the duty to disclose information about risks) would not have prevented the injury, then the breach did not cause the injury.

In battery theory, however, there is no requirement of establishing such a link, for in battery the injury is the unauthorized touching by the physician without invitation, which gives the patient the right to recover damages regardless of the harm that may result from the physician's intervention.[88]

Following *Natanson*, both battery and negligence theories appeared to require the same elements of information disclosure that are necessary for an informed consent; the nature of the procedure, benefits, possible risks, and alternatives. The apparent difference between the two theories, however, concerns the adopted standards of disclosure. While Natanson preferred the"reasonable" or "prudent" practitioner as a standard to determine the scope of information disclosure, battery cases opted for the "lay" or "prudent patient" standard.

The result that emerged from *Natanson* was that by the early 1970s, informed consent knew two different lines of cases. The battery cases that followed the early twentieth-century cases including *Salgo*[89] and negligence cases that relied upon *Natanson* and invoked the principle of self-determination from the early cases as a justification for requiring informed consent under the negligence theory of liability. By adopting the professional practice standard, *Natanson* tempered the courts' dilemma of determining the scope of information disclosure. Courts had already been familiar with the professional standard in ordinary negligence cases, thus they found its application to information disclosure appropriate. This very fact encouraged other courts, after *Natanson* and McCoid's[90] analysis of the issue, to choose negligence analysis, with the adoption of the

professional standard, as the basis of liability in informed consent.

Earlier, it was mentioned that both battery and negligence informed consent cases applied the principle of "discretion" (expressly in *Salgo* and implicitly in *Natanson* by the adoption of the professional standard). The application of this principle in information disclosure led to some controversy. It had become difficult to reconcile the idea of adopting such a principle with that of the patient's right to autonomy.

3 : 5 CANTERBURY: AN ATTEMPT TO REFINE THE DOCTRINE:

The next important development in the doctrine of informed consent occurred in 1972, when three negligence cases, namely; Canterbury v. Spence[91], Cobbs v. Grant[92] and Wilkinson v. Versey[93], introduced some of the battery cases' features into negligence theory; most importantly, the application of the patient-centered or oriented standard of disclosure. These new cases, with the shift to the reasonable person standard, were seen by most commentators as having the potential to offer a defined doctrine of informed consent that provided full protection for the patient's right to self-determination, but this dream did not materialise as the majority of juridictions continued to apply the professional practice disclosure standard.

A-THE CANTERBURY CASE.

Canterbury v. Spence: [94]. The plaintiff in Canterbury underwent a laminectomy for severe back pain. Following the operation he suffered paralysis. A second attempt was made to relieve the paralysis but was unsuccessful. The patient brought an action against

his physician based on the claim that the latter did not warn him of the 1% risk of paralysis that materialized. The appellate court held that the risk of possible paralysis should have been warned of before the patient submitted to the laminectomy.

Once again, *Canterbury* emphasized the principle of self-determination as a justification for requiring the patient's informed consent. Judge Robinson quoted the historical statement of Schloendorff[95];

> "The root premise is the concept...that every human being of adult year and sound mind has a right to determine what shall be done with his own body"[96]

As regards the importance of information disclosure and its sufficiency, the court said:

> "The patient's right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised, only if the patient possesses enough information to enable an intelligent choice"[97].

Moreover, the focus on the principle of self-determination was more carefully expounded in *Canterbury*·Judge Robinson's opinion in the issue included a justification for the legal requirement of information disclosure:

> "True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision. From these almost axiomatic considerations springs the need and in turn the

requirement of a reasonable divulgence by physician to patient to make such a decision possible"[98].

If one starts from the premise that the decision that determines what should be done to his or her own body is the patient's prerogative, it necessarily follows that he or she must reach this decision after a careful consideration of the nature of the proposed therapy, its risks and possible alternative treatments. Thus, the physician is under a legal duty to make a reasonable divulgence about all these facts, a duty which stems from the fiduciary character of the doctor/patient relationship. The court imposed this duty on the physician as part of his or her general duty of care. The court stated that, traditionally, the physician's duty of care invoked information disclosure for proper medical practice. For example, it is common practice that a physician warns the patient about any drug's side effects so that the latter takes precautions when using them. In such an example the duty of information disclosure has a beneficient nature, and when fulfilled, it could be equal, in terms of importance, to a proper diagnosis or proper administration of treatment which are necessary as parts of the general duty of care that the physician owes to his or her patient. Therefore, "due-care normally demands that the physician warns the patient of any risks to his well-being which contemplated therapy may involve"[99].

The apparent conclusion that one may draw is that the court in *Canterbury* called on the principle of self-determination as a primary justification, and the doctor's due-care duty to disclose, for the protection of the patient's right to decide for himself or herself.

In considering the issue of what standard to adopt in determining the scope of information disclosure, *Canterbury* made an historically most significant decision. The court rejected the professional

practice standard, holding that;

> "Respect for the patient's right of self-determination on a particular therapy demands a standard set by law for patients rather than one which physicians may or may not impose upon themselves."[100]

According to the decision, the scope of information disclosure is to be evaluated in terms of criteria established by courts rather than by reference to common practice among other physicians in the professional community. The court reaffirmed the view that the physician is legally required to disclose all material risks inherent in the proposed treatment. In determining which risks are material and therefore ought to be disclosed, *Canterbury* adopted the "prudent patient" test;

> "A risk is thus material 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 determining whether or not to forgo the proposed treatment"[101]

It is worth noting in this respect the objective nature of the test adopted. *Canterbury* did not ask whether the patient himself or herself would have considered the risk, but rather whether a reasonable person in his or her position would have done so. In adopting this test the court reasoned that the professional practice standard of disclosure has the potential of being used as a 'façade' for non disclosure, and that determination of the materiality of risks does not require any special knowledge of medical science.

The court, however, enunciated certain exceptions to the well-established duty of disclosure. One of these, probably the most important,is the principle of "therapeutic privilege". The principle

entitles the physician to use some discretion in disclosing information concerning the risks of proposed treatment "when risk-disclosure poses such a threat of detriment to the patient as to become unfeasible or contraindicated from a medical point of view."[102] To reach this decision the court reasoned that,

> "patients occasionally become so ill or emotionally distraught on disclosure as to foreclose a rational decision, or complicate or hinder the treatment, or even pose psychological damage to the patient"[103]

But the court made it clear that the "privilege does not accept the paternalistic notion that the physician remains silent simply because divilgence may prompt the patient to forgo therapy the physician feels the patient really needs."[104]

Katz[105] observed that, by establishing the principle of therapeutic privilege in information disclosure, the court in *Canterbury* contradicted its attempt to eliminate the professional practice standard of disclosure in informed consent litigation, for the application of this principle as a justification for not warning of certain risks is determined by reference to the professional practice disclosure standard.

Like *Natanson*[106], the court in *Canterbury* reiterated that negligence theory requires that a link be established between the doctor's failure to inform about inherent risks and the injury suffered by the patient. The patient must prove that if the physician had fulfilled his or her duty to disclose these facts, he or she would have decided against the treatment, thereby avoiding the injury suffered. The court, however, rejected the subjective test in examining the credibility of the patient as to the possible decision he or she would have made if informed about all the facts. The court

said;

> "Better it is, we believe, to resolve the causality issue on an objective basis: in terms of what a prudent person in the patient's position would have decided if suitably informed..."[107]

The court believed that the adoption of a subjective test in determining the causation requirement would favour the patient, if that particular patient claims that he or she would not have consented to the proposed treatment had he or she been adequately informed. The court insisted that if the examination of the patient's credibility were carried out according to the subjective test, it would be guesswork, and would subject the physician to the danger of the patient's bitterness. Therefore the court enunciated the objective reasonable person as the only acceptable standard for the establishment of the causation requirement. Accordingly, the patient has to prove that any reasonable person in his or her position would have decided against the treatment if adequately informed. If the patient fails to prove otherwise, he or she will be denied any recovery. In this respect, Katz observed that the court did not resolve the problem of causation as it believed, for the use of such a standard undermined the patient's right to self-determination. He argued;

> "The objective standard of causality contradicts the right of each individual to decide what will be done with his body by denying the patient's recovery whenever his hypothetical decision is out of step with the judgment of a prudent person. The belief that there is one reasonable or prudent response to every situation inviting medical intervention is nonsense....Since different doctors approach similar cases in diametrically opposed ways, equally varying

responses by patients ought to be considered reasonable."[108].

Canterbury reaffirmed that the principle of self-determination is the main justification and goal of informed consent and that the patient's needs for information rather than professionals' practices must determine the appropriate disclosure standard. The court opted for an objective interpretation of these needs using the reasonable person standard. In so doing, however, the court intended to limit patients' informational claims as well as to protect physicians from liability in the practical application of the doctrine to the courtroom setting. According to the standard adopted, only the reasonable person's needs will be considered and legally protected. Therefore if a particular patient's needs differ from those of the reasonable person, his or her right to self-determination will be at stake. *Canterbury*'s choice of the reasonable person disclosure standard, though designed to protect the patient's choice, created controversy and ambiguity. Katz says that this ambiguity manifests "judges' ambivalence towards both patients' self-determination and medical paternalism"[109]. But it seems that in their attempt to resolve this ambivalence courts are much more in favour of the medical profession.[110]

The other two cases; Cobbs v. Grant[111], Wilkinson v. Versey[112], were decided in the same year (1972) and appeared in the same language adopted in *Canterbury*. In *Cobbs*, suffering from an ulcer, the plaintiff consulted Dr Grant who recommended surgery but did not mention the inherent risks of the proposed intervention. An undisclosed risk materialized, causing Cobbs extensive and debilitating injuries. In imposing a duty of information disclosure upon the physician, the court, once again, described the patient as

having an abject dependence on the physician for medical information, and pointed to the necessity of trusting his or her physician to be truthful and completely candid. Because of this dependence which characterized the doctor/patient relationship, the physician has an affirmative duty to disclose "all significant perils"[113]. The court defined these "perils" as "the risk of death or bodily harm, and problems of recuperation"[114]. In *Wilkinson* the court held that"[the] physician is bound to disclose all the known material risks peculiar to the proposed procedure."[115]*Wilkinson* defined "material" as "the significance a reasonable person, in what the physician knows or should know is his patient's position, would attach to the disclosed risk or risks in deciding whether to submit or not to submit to surgery or treatment."[116]

Like *Canterbury*[117]and *Cobbs*[118], the court in *Wilkinson* based the physician's duty to disclose on the patient's need to know, rather than on standard medical practice. The court stated;

> "The patient's right to make up his mind should not be delegated to a local medical group- many of whom have no idea as to his informational needs. The doctor/patient relationship is a one-on-one affair, what is reasonable disclosure in one instance may not be reasonable in another"[119]

This trilogy of decisions followed the contemporary trend that started in the early twentieth century cases and became firmly established after *Salgo*[120]. During this period courts emphasized the patient's right to self-determination as the sole goal of informed consent. Courts reasoned that, in order for a patient to exercise his or her right in self-decision the physician is legally required to provide the patient with a set of information so as to give him or her the opportunity of making a rational and intelligent decision as to

whether to submit to the proposed therapy. This information comprises; diagnosis, prognosis with or without treatment, proposed treatment with the risks inherent therein, and alternative treatments and their risks.

Following *Salgo*, however, courts encountered the problem of finding a suitable and appropriate standard of information disclosure. Their experience in the field evidenced that neither of the standards adopted(whether the professional practice standard adopted in battery cases and in *Natanson*[121], or the reasonable person standard adopted in negligence cases since *Canterbury*[122]) could protect both physicians and patients. In fact most critics focussed on this problem.[123].

B-POST-CANTERBURY: THE TRUMAN CASE

With the exception of the case of Truman v. Thomas[124], no significant development took place during the decade that followed *Canterbury*. The *Truman* case was decided in the same court that had decided the case of *Cobbs*[125] 1972. In Truman the children of a woman who died from cervical cancer, sued their mother's physician for not having warned her of the risk of not undertaking a procedure called the Pap smear test, a procedure that she had repeatedly refused in her life.

Supported by the minority of the court the physician argued that his duty of information disclosure applies only to those treatments to which patients consent, and not to those they refuse. But the court, relying on *Cobbs* which, held that the patient must also be informed of "the risks of a decision not to undergo the treatment"[126], held the physician liable for his failure to warn of the risk of no treatment. The court stated that the duty to warn of the risk of no

treatment[127] resembles the already established duty to disclose alternative treatments to the proposed therapy. The court reasoned that in many instances, no treatment is an alternative to the proposed treatment, therefore the risks of living on without being treated also fall within the scope of the physician's duty of information disclosure in relation to any proffered procedure. To this extent *Truman* had not said anything new. What was new, however, was the application of the duty of information disclosure in the case, despite the patient's refusal of the treatment, and without any bodily intrusion or invasion. The court stated that the kind of decision that the patient makes does not undermine the importance of his or her right to decide what shall be done with his or her own body, arguing that no other result is consistent with the fiduciary character of the physician's duty to inform properly.

This point is legally important for it is incompatible with the theory of battery as a basis of liability, as traditionally understood. The physician can not be held liable for battery without an unauthorized bodily intrusion or touching. The object of information disclosure in battery theory, is the authorization of interventions that would otherwise be instances of battery. Although the early battery cases recognized the patient's right to decide what what was to be done to his or her own body, these cases emphasized the element of consent to physical intrusions.

Contrary to the battery cases, the court in *Truman* did not envisage such physical intrusion when it held that the patient's refusal must be informed. Moreover, because battery theory is associated with physical integrity, it can not acknowledge the importance and value of the patient's decision about medical treatment. In negligence theory, however, as *Truman* demonstrated,

the patient's right to decide can be acknowledged even if he or she decides against some invasion or intrusion. By this move, the *Truman* court intended to reinforce the self-determination justification of informed consent which is not compromised by this limitation of legal theory.[128].

3 : 6 PRESENT POSITION :

Following the landmark decision of *Canterbury*[129], the position of informed consent was one of contrast between the minority of states which have chosen to follow the lead given by *Canterbury*, by adopting the prudent person standard of disclosure, and the majority of states which continued to adopt the professional standard [130]. However, since 1975, there has been a growing tendency for individual states to enact legislation in the informed consent arena.

A-STATE LAWS IN INFORMED CONSENT:

The courts' role in introducing doctrinal advances like that seen in *Truman*[131], has been sharply limited by the involvement of state legislatures in informed consent law.[132] The statutory language in states with legislation on the subject either defined or limited the application of the doctrine of informed consent. Before 1975, only a minority of states had any laws dealing specifically with this subject. However, in 1975 and 1976, coincident with the *Canterbury* decision but resulting from the malpractice insurance crisis[133], a considerable number of states enacted statutes in order to limit or restrict the application of the doctrine of informed consent. The aim of these statutes was to make it more difficult for patients to succeed in their actions against physicians for failure to seek

informed consent. For example, some of these enactments went as far as to create as presumption, rebuttable only on proof of fraud, that the patient's signature is conclusive evidence that an informed consent had been given.[134] In this respect Idaho's statute provides;

> "Such written consent, in the absence of convincing proof that it was secured maliciously or by fraud, is presumed to be valid....and the advice and disclosures of the attending physician or dentist, as well as the level of informed awareness of the given of such consent, shall be presumed sufficient"[135]

In Iowa;

> "A consent in writing to any medical or surgical procedure or course of procedures in patient care which meets the requirements of this section shall create a presumption that informed consent was given"[136].

By 1977 twenty five states had enacted informed consent legislation. The replacement of the common law path to informed consent by statute in thirty states "reflects both the doctrine's high social visibility and the political influence of physicians on state legislatures"[137].

It should be noted that these statutes generally adopted the models supplied by the traditional negligence theory of liability, namely; the professional practice disclosure standard and the objective causation standard. In their study of informed consent legislation Meisel and Kabnick[138], concluded that the number of jurisdictions adhering to the various possible formulations of informed consent theory did not change following the statutory reform, and that therefore the doctrine has remained the way it was under

common law.

3 : 7 CONCLUSIONS:

The main point to note from this analysis of the history of the doctrine of informed consent is that self-determination has been the principle most called upon to justify the physician's obligation to seek the patient's informed consent. Although *Schloendorff*[139] was the first decision to have expressly invoked self-determination, if one considers carefully the language of the cases that preceded this landmark case, in particular the *Mohr* case[140], it can be seen that courts did not expressly use the term self-determination, but they did use terms which have the same function[141].

On the other hand, the language rarely appears in case law, but specific forms of justification can be determined from the precedents cited, and from the applied theory of liability. Battery theory for example, has a natural justification in respect for self-determination interpreted as the right of the patient not to be touched unless he or she authorizes such intrusion. But negligence theory in informed consent cases may have more than one justification, for the law of medical malpractice is based on the principle of beneficence. The law of malpractice imposes upon physicians a duty to do what will promote patient well-being through the exercise of reasonable skill and care. But as has been said,

> "although negligence treatment cases are firmly linked to beneficence-based concerns, 'informed consent' negligence cases have had strong ties to the principle of respect for autonomy."[142]

However, because of other concerns that courts had to confront, sometimes self-determination had been tempered or even ignored. Very

often these concerns or interests were beneficence-based considerations of patient welfare. Therapeutic objects, for example, courts believed had to prevail over the patient's right to decide what should be done with his or her own body. But courts have been severely criticised for this tendency to protect the patient's welfare rather than his or her right to self-decide.

In other instances, the law had been turned away from its basic role of protecting the patient's right to self-decide because of the mechanics and pragmatic constraints that the legal process contains, e.g., the causation requirement in negligence, and the proof of unauthorized touching in battery. In order to recover damages, the patient has to provide a proof of abuse only after the fact, and that proof has to satisfy the the courtroom's procedural rules.

In any event, even if the doctrine of informed consent did not succeed in fully protecting the patient's right to self-determination, at least it has succeeded in bringing the issue to public attention.

On the basis of this analysis, one will turn now to look at the issue of consent under the British legal system. It is submitted that British courts did not adopt the doctrine of informed consent the way it emerged in the U.S, but the doctrine has certainly influenced British courts in one way or another.

NOTES:

1-See supra chapter one.

2-See infra chapter four p 127.

3-See, White, W.D., "Informed consent: ambiguity in theory and practice", 8 Jour. Health, Politics, Policy and Law (1983) p 101.

4-Schloendorff v. Society of the New York Hospital, 105 N.E 92 (1914).

5-Rational in this context refers to intelligence and reason, i.e., ageeable to reason.(Chambers Twentieth Century Dictionary). In this discussion, "rational" and "intelligent" will be used as synonymous.

6-For discussion see, Aplbaum, P.S., Lidz, C.W. & Meisel, A., Informed consent: Legal Theory and Clinical Practice, New York, Oxford University Press, 1987, Chap 3. See also, Waltz, John R., and Sheuneman, Thomas W., "Informed Consent to Therapy" 64 Northwestern University Law Review (1969) p 628. Zaslow, J., "Informed Consent in Medical Practice", 22 The Practical Lawyer (1976) p 13, See also Robertson, G., "Informed Consent to Medical Treatment", 97 L.Q.R. (1981) p 102, Weyandt, C.J., "Valid Consent to Medical Treatment: need the patient know?", 4 Duquesne University Law Review (1965-66) pp 450.

7-Slater v. Baker & Staplton 95 Eng.Rep. 860 (K.B 1767), 2 Wils. K.B 359 [1767]

8-2 Wils K.B 359 [1767], at p 362 .

9-Wells v. World Dispensary Medical Association, 120 N.Y 630, 24 N.E 276 (Ct. App N.Y 1890).

10-Pernick, Martin S., "The patient role in medical decision-making: A social history of informed consent in medical therapy", in: President's commission for the study of ethical problems and

biomedical and behavioral research. Making Health care decisions. vol.3, 3 (Washington; U.S Government Printing Office 1982).

11-Ibid p 3.

12-Ibid p 11.

13-Ibid p 11,12.

14-Faden, R., & Beauchamp, T., A History and Theory of informed consent, New York, Oxford University Press, 1986, p 78.

15-Id.

16-Wood, J., Case Report, 11 Boston Medical and Surgical Journal (1834), p 275

17-Bard, D.M., "History of a Polypoys Excrescence in the Vagina, Attended with Unusually Severe Symptoms", 2 Boston Medical and Surgical Journal 34 (1829).

18-Faden and Beauchamp, op.cit, p 78.

19-Ibid p 81.

20-Schloendorff v. Society of N.Y Hospitals. supra.cit.

21-Anonymous, "Why are Malpractice Suits", 200 N.E.J.M (1929) p 93.

22-Stetson, Halbert G., & Moran, John. F., "Malpractice Suits: their cause and Prevention", 210 N.E.J.M (1934) pp 1883-84.

23-Annotation, "Consent as condition of right to perform surgical operation", 76 American Law Report 562 (1932).

24-Report, "Trial of a physician for assault and battery" 38 Boston Medical and Surgical Journal 528 (1848).

25-Id.

26-Faden and Beauchamp, op.cit, p 120, for further discussion see in the same reference, Chapt 2, McCoid, "A Reappraisal of Liability for Unauthorized Medical Treatment" 41 Minnesota Law Review (1957) p 381, Winston Smith, Herbert, "Antecedent Grounds of Liability in the Practice of Surgery", 14 Rocky Mountain Law Review (1942) pp

233-55.

27-See Prosser, W., Handbook of the Law of Torts, St. Paul West Pub. Co. (4th.ed) 1971, p 102-06 .

28-Faden and Beauchamp, op.cit, p 120.

29-See Mc Coid, op.cit, pp 381,382-434. See also, Stewart, Terry, "The Doctrine of Informed consent" 43 Insurance Counsel Journal (1976) p 118.

30-Mohr v. Williams 95 Minn 261, 104 N.W 12 (1905).

31-Patts v. Davis 224 Ill 300, 79 N.E 562 (1906).

32-Roleter V. Stain, 39 Okla 572, 137 P.96 (1913).

33-Schloendorff v. Society of N.Y Hospitals. 211 N.Y 125, 105 N.E 92 (1914).

34-Mohr v. Williams 95 Minn 261, 104 N.W 12 (1905).

35-104 N.W 12 (1905) at p 14.

36-Ibid p 15.

37-Faden and Beauchamp, op.cit, p 121.

38-104 N.W 12 (1905) p 15.

39- Faden and Beauchamp, op.cit, p 121.

40-Pratts v. Davis: 224 Ill 300, 79 N.E 562 (1906).

41-See for example 118 Ill. App. 161 (1905) p 166.

42-See 79 N.E 562 (1906) at p 565.

43-Rolater V. Strain 39 Okla 572, 137 P.96 (1913).

44-See Faden and Beauchamp, op.cit, p 123.

45-SChloendorff v. Society of N.Y Hospitals: supra.cit.

46-Ibid p 93.

47-See Faden and Beauchamp, op.cit, p 124.

48-Id.

49-For example in, Perry v. Hodson 168 Ga.678, 148 S.E 659 (1929), Donald v. Swann 24 Ala.App 463, 137 SO 178 (1931). Wall v. Brim,

138 F.2nd 478 (5th Cir. 1943). Keen v. Coleman 67 Ga.App.331, 20 S.E 2nd 175 (1942). Buck v. Bell, 274 U.S 200 (1927), a case involving complsory sterilization. Marshall v. Harter 262 SW 2nd 180(Ky. Ct. App 1953). Chambers v. Nottebaum 96 SO 2nd 716, Fla.Dist.Ct.App (1957). Keister v. O'neil 59 Cal.App 2nd 428, 138 P.2nd 723(1943), for further discussion of battery cases, see Kelly, William A, "The Physician, The Patient, And The Law" 8 Kans L.R (1960) p 405.

50-See Applbaum, Lidz and Meisel, op.cit, p 38.

51-Id.

52-Id.

53-Salgo v. Leland Stanford Jr University Board of Trustees, 154 Cal. App 2nd 560, 317 P.2nd 170 (1957).

54-317 P 2nd 170 (1957) p 181.

55-Ibid p 181.

56-Myers, Mickael Justin, "Informed consent in Medical Malpractice" 55 California Law Review (1967) p 1403.

57-See for example, Roberts v. Wood, 206 F.Supp.579, 582 (S.D.Alas 1962).

58-See Faden and Beauchamp, op.cit, p 126.

59-Id.

60-See Myers, Mickael Justin, op.cit, p 1403, this confusion was also observed by Katz, Jay in his article, "Informed Consent: A Fairy Tale? Law's vision", 39 University of Pittsburgh Law Review 138 (1977). He refers to it as a clear or typical example of judicial dilemma that lies in the heart of informed consent. He says, "[o]nly in dreams or fairy tales can 'discretion' to withhold crucial information so easily and magically be reconciled with full disclosure" at p 138.

61- For further discussion see, Plante, Marcus L., "An analysis of informed consent", 36 Fordham Law Review (1968), pp 639, see also Katz, op.cit, p 138-9.

62-McCoid, op.cit, at p 434.

63-Id.

64-Ibid pp 424-27.

65-Faden and beauchamp, op.cit, p 128.

66-Id.

67-Gray v. Grunnagle 423 Pa.144, 223 A 2d 663 (1966).

68-Berkey v. Anderson 1 Cal.App 3d 790, 82 Cal. Rptr.67 (1966).

69-See 82 Cal.Rptr.67 at p 77, and 1 Cal. App. 3rd at p 805 (1966).

70-1 Cal.App 3rd (1966) PP 805.

71-For discussion see Meisel, Allan, "The Expansion of liability for Medical accidents: from negligence to strict liability by way of informed consent", 56 Nebraska L.R (1977) pp 79.

72-Cooper v. Roberts 229 Pa.Supp.260, 286 A.2d 647 (1977).

73-See 286 A 2d (1971) p 647.

74-Ibid p 650.

75-Faden and Beauchamp, op.cit, p 129.

76-McCoid, A., "A Reappraisal of Liability for Unauthorized Medical Treatment" 41 Minnesota Law Review 381 (1957).

77-Natanson v. Kline 186 Kans 393, 350 P.2nd 1093, opinion on denial of motion for rehearing, 187 Kans 186, 354 P.2nd 670 (1960).

78-Id.

79-354 P.2nd 670 (1960) at p 673.

80-Salgo v. Leland Stanford Jr University Board of Trustees, 154 Cal.App 2nd 560, 317 P 2nd 170 (1957).

81-Mohr v. Williams 95 Minn 261, 104 N.W 12 (1905).

82-354 P.2nd 670 (1960) at p 675.

83-Ibid at p 673.

84-Faden and Beauchamp, op.cit, p 131.

85-See Applbaum, Lidz and Meisal, supra.cit, at p 121, see also Plante, "An analysis of informed consent", op.cit, pp 639, Waltz and Scheuneman, loc.cit, p 646-48.

86-350 P.2nd 1093 (1960) at p 1106.

87-Cobbs v. Grant 104 Cal.Rptr.505, 502 P.2nd 1 (1972), a case that followed Canterbury in both chronology and reasoning.

88-For discussion of differences between battery and negligence cases see, Faden and Beauchamp, op.cit, Chap.2, p 23, see also Plante, loc.cit p 639, Robertson, G., loc.cit, at pp 106-07.

89-Salgo v. Leland Stanford Jr University Board of Trustees, 154 Cal. App 2nd 560, 317 P.2nd 170 (1957).

90-McCoid, loc.cit, p 381.

91-Canterbury v. Spence 464 F.2nd 772 (D.C Ci. 1972).

92-Cobbs v. Grant 104 Cal. Rptr. 505, 502 P 2d 1 (1972).

93-Wilkinson v. Versey 295 A 2d 676. (R.I 1972).

94-Canterbury v. Spence 464 F.2nd 772 (D.C Ci. 1972).

95-105 N.E 92 (1905).

96-464 F.2nd 772 (D.C Ci 1972) at p 780, (citing Schloendorff, 105 N.E at p 93.)

97-Ibid at p 786.

98-Ibid at p 780.

99-Ibid at p 786.

100-Ibid at p 780.

101-Ibid at p 787, the court seems to agree with Waltz and Scheuneman in the use of the "reasonable or prudent person" test which had already been suggested two years before Canterbury's decision, see Waltz and Scheuneman, loc.cit, p 140.

102-464 F.2nd 772 (D.C Ci 1972) at p 789.

103-Ibid at p 789.

104-Id.

105-See Katz, Jay, loc.cit, p 157.

106-350 P.2nd p 1104.

107-464 F.2nd 772 (D.C Ci 1972) at p 791.

108-Katz, loc.cit, at pp 163.

109-Ibid p 157.

110-Id.

111- Cobbs v. Grant 104 Cal.Rptr.505, 502 P.2d 1 (1972).

112-Wilkinson v. Versey 295 A.2nd 676 (R.I 1972), 8 Cal.3d 229, 502 P.2d 1 (1972).

113-502 P.2nd 1 (1972) at p 12.

114-Ibid p 11.

115-See 295 A.2nd 676 (R.I 1972) at 688.

116-Ibid p 689, (citing Waltz and Scheineman).

117-464 F.2nd 772 (D.C Ci. 1972).

118-104 Cal.Rptr.505, 502 P.2nd 1 (1972).

119-The same decision had been taken in Canterbury but in another way;

> "Respect for patient's right of self-determination on particular therapy demands a standard by law rather than one which physicians may or may not impose upon themselves." 464 F.2nd 772 (D.C Ci. 1972) at p 780.

120-157 Cal.App 2nd 560, 317 P.2nd 170 (1957).

121-Natanson v. Kline 186 Kans 393, 350 P.2nd 1093, opinion on denial of motion for rehearing, 187 Kans 186, 354 P.2nd 670 (1960).

122-464 F.2d 772 (D.C Ci. 1972).

123-See for example, Hill, D.H., "Whither informed consent?", 229 J.A.M.A (July 1974) pp 305-310, Comment "Informed Consent; a Proposal Standard of Medical Disclosure", 48 New York University

Law.Rev (June 1973), pp 548-63, Plante, M., "The Decline of Informed Consent", 35 Washington & Lee Law Review (Winter 1978), p 91-105, Katz, loc.cit, at p 154-58, see also White W.D, loc.cit, p 99

124-Truman v. Thomas 165 Cal.Rptr.308, 611 P.2nd 902 (Cal.1980).

125-104 Cal.Rptr.505, 502 P.2nd 1 (1972).

126-611 P.2nd(1980) at p 906, quoting Cobbs, 502 P.2nd (1972) at p 10.

127- The court in Truman regarded this duty as already established by Canterbury (the duty to inform about the risks of no treatment).

128-See Faden and Beauchamp, op.cit, 139.

129-464 F.2nd 772 (D.C Ci. 1972).

130-For a detailed list of the states adopting the majority approach and those adopting the minority approach see, generally Seidelson, C., "Medical Malpractice: informed consent in full disclosure juridictions", 14 Duq. L. R. 309 (1976).

131-Truman v. Thomas 165 Cal.Rptr.308, 611 P.2nd 902 (Cal.1980).

132-See Faden and Beauchamp, supra.cit, p 139, see also Plante, "The Decline of Informed Consent", op.cit, p 91. See also Annas, J.G, Glantz, L.H. & Katz, Barbara, Informed Consent to Human Experimentations: The Subject's Dilemma, Ballinger Publishing Comp. 1977, p 38.

133-For discussion of Malpractice Insurance Crisis, see Annas, J.G. et al., "Medical Malpractice Litigation Under National Health Insurance; essential or expendable?", (1975) Duke Law Journal 1335.

134-The states concerned with this presumption are, Colorado, Florida, Iowa, Idaho, Nevada, North Carolina, Ohio, Utah and Washington.

135-Idaho Code 439-4305.

136-Iowa Code Ann, Ch 147 (added by H.B 803, 16. 1975)

137-See Faden and Beauchamp, op.cit, p 139.

138--See Meisel, A., and Kabnick, L.D., "Informed consent to medical treatment: an analysis of recent legislation" 41 University of Pittsburgh Law Review 407 (1980).

139-SChloendorff v. Society of N.Y Hospitals: 211 N.Y 125, 105 N.E 92 (1914).

140-Mohr v. Williams 95 Minn 261, 104 N.W 12 (1905).

141-See the discussion of the *Mohr* case above p 86.

142-Faden and Beauchamp, op.cit, p 141.

CHAPTER FOUR

THE CONSENT DOCTRINE IN THE U.K

It is against the historical analysis of the transatlantic doctrine of informed consent outlined in chapter three that one will turn now to consider the issue under British law. It should be reiterated at this stage that informed consent is not part of British law. This view has been confirmed in Sidaway v. Bethlem Hospital Governor & Ors.[1]

Nevertheless, it should be noted that British courts did not ignore the issue of consent and its fundamental elememt of information disclosure. It is submitted that the first English case that imposed a legal duty upon the physician to provide his or her patient with the needed information and particularly that relating to the risks inherent in the proposed treatment, was Chatterton v. Gerson[2]. Before considering this landmark case, it would be convenient to examine the status of consent before this decision.

4:1 NOTION OF 'REAL' CONSENT:

The law is well settled under the British legal systems that, before a physician may approach or treat a patient, he or she must seek the consent of the patient if he or she has the mental capacity of giving it. If not, the consent of his or her guardian will be sufficient, unless the doctor intervenes in an emergency situation which requires immediate attention for the preservation of the patient's life or health.[3] The touching of another person's body without his or her consent constitutes a tort/delict.[4]

It is also the rule that for consent to be valid, it must be 'real' in the sense that the patient must be aware of what he or she is exposing his or her bodily integrity to. In order to have this aspect, the patient's consent must be based on certain information that the physician must disclose in relation to 'the general nature and purpose of the proposed procedure'.[5] The application of this can be seen in the dictum of Bristow J in Chatterton v. Gerson[6], where he said;

> "In my judgment once the patient is informed in broad terms of the nature of the procedure which is intended, and gives her consent, that consent is real..."[7] (emphasis added)

The phrase 'the general nature and purpose of the proposed treatment' is ambiguous, however. It does not determine, for example, as Robertson[8] remarked, whether or not information relating to the risks inherent in the proposed treatment is also part of 'the general nature and purpose of the proposed treatment.' In other words it does not show whether the doctor is also legally required to disclose information relating to the risks associated with the administration of the treatment. Two cases decided chronologically before *Chatterton*, however, seem to give no support for the proposition that a legal duty is incumbent on the doctor to inform his or her patient of the risks inherent in the proposed treatment. These were Hatcher v. Black[9] and Bolam v. Friern H.M.C[10].

Hatcher v. Black[11]

In this case, the plaintiff Mrs Hatcher, who occasionally broadcast for the B.B.C, consulted her doctor seeking treatment for a toxic thyroid gland. An operation was advised. The patient asked her

doctor if there was any risk to her voice. The latter reassured her that there was not.

After the operation, the patient's left vocal chord was paralyzed and she could not speak properly any more. In a claim for damages, the patient alleged that her physician was negligent in not warning her of the risk of damage to her voice.

During the trial, Denning L.J (as he then was) instructed the jury that the doctor should not be held liable for negligence just because he had admitted telling the patient that the intervention involved no risks, when he knew that there was a slight risk. The only situation in which the doctor might be held liable is when the jury are satisfied that he or she had fallen bellow the standard of a reasonably skilful doctor[12], i.e., where it could be evidenced that a reasonable doctor would have warned his or her patient of such a risk under the same circumstances. Denning also instructed the jury that the decision as to whether to disclose information relating to the risks inherent in the proposed treatment was a matter for the doctor's own medical judgment.

It should be noted therefore that according to the decision in *Hatcher*, the doctor is legally required only to act in accordance with routine and accepted practice. And the question of whether he or she is also required to disclose information relating to the risks inherent in the proposed therapy is one "not of law, but one of reasonable medical judgment"[13]

In another case the court relied upon the notion of clinical judgment in assessing whether or not disclosure has been sufficient. That was in the *Bolam* case.

Bolam v. Friern H.M.C[14]

Suffering from mental illness, the patient in this case was subjected to an electro-convulsive treatment without being warned of the risk of fracture involved in the procedure, and without the use of relaxant drugs. There was evidence, however, that the risk of fracture was very small.

Expert testimony evidenced that were two accepted methods of administering the treatment in question; Some physicians preferred the use of relaxant drugs, whereas others were of the opinion that the use of such drugs was attended by risks and confined the use of these drugs to cases where there were particular reasons for their use. The plaintiff was not such a case. After the administration of the treatment, the patient sustained fractures and subsequently sued his physician for negligence in the administration of the treatment and in failing to warn him of the risk involved before the treatment was give.

As in *Hatcher*, the court in this case expressed the view that the doctor was entitled to proceed without explanation of the risks in the light of the patient's condition. In instructing the jury, the judge said;

> "...you may well think that when a doctor is dealing with a mentally sick man and has a strong belief that his only hope of cure is submission to electro-convulsive therapy, the doctor can not be criticized if he does not stress the dangers, which he believed to be minimal, which are involved in their treatment..."[15]

It was also stated that, being entitled to administer the treatment according to the school of thought which preferred not to use a relaxant drug, the physician was not negligent in not warning

his patient of the small risk of fracture. On the other hand there was evidence that the patient was severely depressive and might not have been in a position to understand whatever explanation the doctor had made.

In sum, the court reaffirmed that the question of whether a physician is required to inform his or her patient of the risks inherent in the proposed treatment was a matter of medical judgment.

The same approach has been adopted in the influential New Zealand case of Smith v. Auckland Hospital Board.[16] The patient in this case alleged that he has not been informed properly before undergoing an aortagram, in particular of the risks involved in the procedure. In a dictum which has since been widely referred to in the British courts, the court mentioned certain factors that should be taken into consideration when informing the patient,

> "...., the paramount consideration is the welfare of the patient and, given good faith on the part of the doctor, I think the exercise of his discretion in the area of advice must depend upon the patient's overall needs. To be taken into account should be the gravity of the condition to be treated, the importance of the benefits to be expected to flow from the treatment or procedure, the need to encourage him to accept it, the relevant significance of its inherent risks, the intellectual and emotional capacity of the patient to accept the information without such distortion as to prevent any rational decision at all, and the extent to which the patient may seem to have placed himself in his doctor's hands with the invitation that the latter accept on his behalf the responsibility for intricate or technical decision"[17]

The approach adopted in Chadwick v. Parsons[18], however, has been considered as the first sign that English courts might impose a general duty similar to that of the transatlantic 'doctrine of

informed consent.'[19] In this case the plaintiff successfully sued her physician following the severe injuries she suffered as a result of undergoing an experimental intervention in an attempt to cure her deafness. Her action was based on the allegation that the doctor was negligent in not informing her of the risk of injury inherent in the intervention. But, because the physician admitted liability, the court did not have the opportunity of considering the physician's duty relating to the disclosure of information.

In other cases, courts followed the approach adopted in *Hatcher*[20] and *Bolam*[21], i.e., that the doctor is legally required to act in accordance with standard medical practice, and that information relating to the risks inherent in the proposed treatment is given according to what the reasonable medical practitioner would disclose. In O'Malley-william v. Board of Governors of of the National Hospital for Nervous Diseases[22] the patient suffered permanent partial paralysis of the right hand following an aortagram, an exploratory intervention carried out by inserting a needle into the patient's arteries. His action was also based on the allegation that the physician failed to warn him of the potential risk of the procedure, in this case paralysis. The court was satisfied by expert testimony that the risk of the paralysis that materialized was a remote one, and stated that failure to warn of a remote risk did not constitute negligence.[23] The court, however, did not discuss whether failure to warn of a real risk constituted negligence.

The main aspect that characterized courts' decisions in the cases mentioned above is that there was no express or positive statement that shows whether the physician is legally required to disclose information relating to the risks inherent in the proposed treatment. By so doing, courts neglected an important issue that needed adequate

examination.

4:2 CHATTERTON: NEGLIGENCE AND THE LEGAL DUTY TO WARN OF RISKS:

The silence that characterized courts' decisions concerning the issue of whether there was a positive duty on doctors to keep their patients informed of all aspects of their treatment, even if they do not raise this question themselves, was broken in the decision of the High Court in Chatterton v. Gerson.[24] In this case, the court imposed a legal duty upon the physician to inform his or her patient of the risks inherent in the proposed treatment, a duty similar to that of the transatlantic doctrine of 'informed consent'.

THE CHATTERTON CASE:

The patient in Chatterton suffered pain from a post-operative scar in her groin. She was referred to the defendant who was a specialist in the treatment of chronic intractable pain. In an attempt to relieve the pain, the defendant performed two operations on her. But neither of the two interventions succeeded in relieving the pain. In addition the plaintiff found that her right leg was completely numb, which considerably impaired her mobility.

She based her claim for damages, for negligence and trespass, on the allegation that the defendant had failed to warn her of the inherent risk of loss of sensation. In dismissing the claim in negligence the court held;

> "....there is no obligation on the doctor to canvass with the patient anything other than the inherent implications of the particular operation he intends to carry out. He is certainly under no obligation to say

> that if he operates incompetently he will do damage. The fundamental assumption is that he knows his job and will do it properly. But he ought to warn of what may happen by misfortune however well the operation is done, if there is a real risk of a misfortune inherent in the procedure..."[25] (emphasis added)

It can be seen from the dictum above that the court imposed a legal duty upon the physician to inform his or her patient about the risks associated with the administration of the proposed treatment. The physician is required to disclose only 'real risks', however. It has been pointed out that by using the term 'real risks' and adopting the standard negligence formula, the court implicitly suggested that the doctor's duty to disclose the 'real risks' of the proposed procedure stems from his or her general duty to exercise due care in the treatment of the patient[26]. The court made it clear in *Chatterton* that failure to provide adequate disclosure of the risks inherent in the proposed treatment is to be considered as a breach of the physician's duty to his or her patient, and must therefore be treated under negligence theory. In this respect the court said;

> "...it would be very much against the interests of justice if actions which are really based on failure by the doctor to perform his duty adequately to inform were pleaded in trespass" [27]

The shift to the negligence rather than the assault action has been said to be appropriate, but as Robertson pointed out;

> "To regard the obligation to disclose 'real risks' as part of the doctor's overall duty of care places too much emphasis on the doctor's duty to to disclose and insufficient emphasis on the patient's right to receive"[28]

In addition, the plaintiff, in a claim for negligence based on the

doctor's failure to warn of inherent risks, must establish causation. The principle suggests that the plaintiff must prove that his or her consent would not have been granted, had the required information been communicated.

4:3 SIDAWAY: STANDARD OF INFORMATION DISCLOSURE:

The main issue after *Chatterton*[29] was concerned with the establishment of the appropriate standard to determine whether or not the particular risk is a real one, and must therefore be warned of. As mentioned earlier, the trend now is that actions based on lack of consent to medical treatment should be taken in negligence. British courts have generally opted for the professional medical standard that was enunciated in *Bolam*.[30] It was not clear, however, whether the *Bolam* principle applied equally to diagnosis and treatment and to the giving of information. That it did so was confirmed in *Chatterton* where it was held;

> "The duty of the doctor is to explain what he intends to do, and its implication, in the way a careful responsible doctor, in similar circumstances would have done."[31]

In Hills v. Potter[32], Hirst J rejected any form of the doctrine of informed consent as having no place in English law and adopted the medical test. The same approach has been taken by Tudor Evans J in Sankey v. Kensington and Chelsea Area Health Authority[33]. However, the most important decision on this issue came from the House of Lords in the *Sidaway* case in which the court had the opportunity to discuss the question of consent and the tests that must be applied.

Before going any further, it should be noted that the House of

Lords' decision in *Sidaway*, it is said[34], now represents the law of the United Kingdom on the issue, although one scholar[35] maintains that the case in question does not mark "the end of the controversy over how much the doctor must tell,"[36] and that all that the majority in the House of Lords achieved was the confirmation that the 'informed consent' test, i.e., what the patient should be told, should be judged by what the reasonable patient would want to know, was not part of British law. There are, however, subsequent cases which confirm the former rather than the latter view.[37]

Sidaway v. Bethlem Hospital Governors and Others[38]:

The facts were that the plaintiff, who suffered from persistent pain in her neck and shoulders, was advised by a surgeon employed by the defendant hospital governors to operate on her spinal column to relieve the pain. The surgeon warned the patient of the possibility of disturbing a nerve root and the possible consequences of doing so, but did not mention to her the possibility of damage to the spinal cord. There was evidence that the risk of damage to the spinal cord was a small one (less than 1%). If the risk materialized, however, the resulting injury could be severe. The patient consented to the intervention in the course of which she suffered injury to her spinal cord resulting in her being disabled.

The patient sued both the surgeon and the Maudsley Hospital for negligence. She did not question the surgeon's skill or capacity to operate. Rather she maintained that the surgeon had never mentioned to her the risk of injury to the spinal cord. But as the surgeon died before the action came to trial, the courts had been deprived of the vital evidence as to exactly what information the surgeon disclosed to

Mrs Sidaway, and what reasons, if any, he had for withholding the rest of information from her.

In dismissing her claim in negligence, the High Court proceeded from the inference that the surgeon would have followed his customary practice, that is, he would have informed his patient in general terms of the possibility of injury to a nerve root but would not have mentioned the risk of damage to the spinal cord.

Mrs Sidaway also claimed damages in battery on the basis that the surgeon's failure to warn her of the risk of injury to the spinal cord invalidated her consent. In dismissing her claim in battery, the High Court followed the approach discussed earlier, namely that failure to give full information would not render a procedure a battery providing the patient understands the general nature of the procedure.

On appeal, the Court of Appeal upheld the decision of the High Court, holding that the doctrine of informed consent based on full disclosure of all the facts to the patient was not the appropriate test under English law. Mrs Sidaway appealed to the House of Lords.

Once again the House of Lords endorsed the traditional test enunciated in the case of *Bolam*[39], i.e., the doctor's duty to advise and warn his or her patient was part and parcel of his or her general duty of care in the treatment of the patient. And the doctor would have fulfilled his or her duty of information disclosure, when he or she conformed to a responsible body of medical opinion in deciding what to disclose and what not to disclose to the patient. Lord Diplock said that the *Bolam* test should be applied in the context of disclosure as well as in that of treatment and diagnosis;

> "To decide what risks the existance of which a patient should be voluntarily warned [about] and the terms in which such warning, if any, be given, having regard to the effect the warning may have is as much

> an exercise of professional skill and judgment as any other part of the doctor's comprehensive duty of care to the individual patient, and expert medical evidence on this matter should be tested in just the same way."[40]

In Sidaway, there was evidence that while some neuro-surgeons might warn some patients of the risk to the spinal cord, many preferred not to. The plaintiff lost her case.

It is noteworthy that while maintaining the professional standard of information disclosure, the House of Lords brought some modification to the existing law in certain aspects. In this respect, Lord Bridge said;

> "A judge might, in certain circumstances come to the conclusion that the disclosure of a particular risk was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it."[41]

This view suggests that the courts retain ultimate control of the definition of the physician's duty to inform. That is, even when the overwhelming body of medical opinion accepted non disclosure of a particular risk, Lords Bridge and Templeman asserted the judicial right to intervene where disclosure was obviously necessary for the patient to make a rational decision as to whether to undergo the proposed procedure.

Only Lord Scarman rejected the professional medical standard as the test of what should be disclosed to the patient. His rejection stems from his recognition of the patient's right to self-determination, and his or her right to decide what shall be done with his or her own body. For Lord Scarman, it is the patient's right to know which makes the issue of advice given the to patient distinct

from other aspects of medical care. Accordingly, the physician should be held liable if he or she "omits to warn where the risk is such that in the court's view a prudent person in the patient's situation would have regarded it as significant"[42]. However, Lord Scarman entitles the doctor to withhld information as to risk if it can be established that "a reasonable medical assessment of the patient would have indicated to the doctor that disclosure would have posed a serious threat of psychological detriment to the patient"[43]. Although Lord Scarman recognized the patient's right to be informed of all material risks, he too found against Mrs Sidaway. He said that the plaintiff failed to prove that the less than 1% risk was such that a prudent patient would consider it significant. In addition the death of the surgeon made it difficult for the court to know his medical assessment of Mrs Sidaway and her state of mind before he operated on her.

THE DUTY TO ANSWER QUESTIONS:

One aspect of the information issue that has been confirmed as aresult of Sidaway deals with the issue of the curious patient. According to the judgments of the Law Lords, when questioned specifically by the patient about risks involved in the proposed procedure, the physician must answer as truthfully and as fully as the questioner requires[44]. This principle has been upheld in the more recent case of Blyth v. Bloomsbury Health Authority.[45]

In this case the patient who suffered prolonged bleeding after receiving Depo-Provera, a long term contraceptive, succeeded in recovering damages. Although the patient has asked specific questions about the proposed treatment, she was not informed of the drug's side effects.

4:4 POST-SIDAWAY: NON-THERAPEUTIC CONTEXT:

There are various references in the argument and judgments in the Sidaway case, to the 'healing' or 'therapeutic' context in which that case was decided. Does the same approach followed in Sidaway, i.e., the adoption of the professional standard of information disclosure, also apply in instances where the patient needs advice about an elective procedure and the options involved in, for example, non-therapeutic context like cosmetic surgery or birth control?. This qhestion was raised in the case of Gold v. Haringey Health Authority.[46]

The facts of this case were that when, in 1979, the plaintiff, Mrs Gold, entered her third pregnancy she and her husband decided to have no further children after that one. She consulted the defendant physician for advice. The latter told her that a sterilisation would be arranged for her but mentioned nothing about other contraceptive options and the failure rate of sterilisation. There was evidence that in 1979 there was a responsible body of medical opinion that would not have spoken of the other options or the failure rate.

At first instance the judge said that the *Sidaway* case was decided in a therapeutic context and that he was concerned with a different situation where the patient asked for advice as to methods of contraception and was told that sterilisation was the appropriate procedure for her without being informed of the other options, and without being warned of the risk of failure.

It was held that in that context the adequacy of what she was told was to be determined not by reference to prevailing medical practice but by the court's view as to whether the person giving advice-who might be a hospital doctor, a general practitioner, or a counsellor at a family planing clinic or a health visitor-acted negligently. The

court found that there was a duty upon the doctor concerned to mention the other options and the failure rate, a duty that the defendant had not fulfilled.

The Court of Appeal, however, took a different view.[47] The appellate court held that the distinction the judge drew at the first instance between therapeutic contexts, where the Bolam principle applied, and non-therapeutic contexts such as contraceptive counselling, was "unwarranted and artificial."[48] The fact that medical practice as to warning was divided at the time of Mrs Gold's srerilisation meant that a doctor who did not warn could not be held liable in breach of his duty.

The result of this decision is that , even in the context of counselling a healthy adult as to methods of birth control, her right to information to help her decide is governed solely by what the profession is willing to tell her, and the court will not assert any other right to information on her behalf. So long as there are some doctors, sufficient to constitute a responsible body of medial opinion, who give only a limited or no disclosure (in this or in any other context), such disclosure will be declared by the court to be consistent with the patient's right.

4:5 THE WAY FORWARD:

The way the law of consent to medical treatment developed in this country and particularly following the decision in *Sidaway*[49] seems to suggest that British courts are and will probably be always in favour of the principle enunciated in *Bolam*[50], and medical paternalism. That is, it is the medical profession that decides for the patients what they need to know concerning their treatment. Needless to say, such a position goes counter to the patient's right

to autonomy and self-determination.

The courts' opting for the medical standard and medical paternalism reflects, in part, their desire to avoid what followed the development of the doctrine of informed consent in the United States, namely, the malpractice crisis and the practice of defensive medicine.[51]

The fear of developing a similar crisis in Britain has influenced British courts very strongly. Dunn, L.J., for example, considered that the adoption of the doctrine of informed consent "would be damaging to the relationship of trust between doctor and patient, and might well have an adverse effect on the practice of medicine."[52]

As mentioned earlier the law opted for current medical practice to judge whether the particular doctor has fulfilled his or her duty of information disclosure. This certainly works in favour of doctors. But the law has also recognized the judicial right to intervene in exceptional cases.[53] This recognition will encourage many patients to continue go to courts over informed consent claiming that their case is an exceptional one.[54] As has been pointed out, "[l]imiting liability to exceptional cases of non-disclosure...will not stem the flood of litigation, [i]t will make litigation more acrimonious."[55]

4:6 CONCLUSIONS:

So far in Britain, the law recognizes that the person has a right to choose what shall be done with his or her own body, and therefore he or she must consent to medical treatment or it will be trespass to the person.

It is also established that consent to the nature of the procedure is enough to preclude an action in battery.[56] Failure to provide the patient with sufficient information to make a rational and 'informed'

decision as to whether to agree to the proposed treatment, must be litigated in negligence.[57] In *Chatterton* it was held that;

> '... justice required that in order to vitiate the reality of consent there must be a greater failure of communication between doctor and patient than that involved in a breach of duty if the claim is based on negligence"[58]

That is the doctor's duty to inform stems from his or her general duty of care due to the patient, but not from the patient's 'right to know'. It follows that the doctor cannot be held liable in negligence if he or she fails to inform of particular risks as long as he or she acts, when fulfilling his or her duty of information disclosure, "in accordance with a practice accepted as proper by a responsible body of medical men skilled in [the] particular art."[59] That is to say that the principle also applies as a standard for information disclosure. This was confirmed in the decision of the House of Lords in the case of Sidaway.[60] Accordingly, the amount of information that should be disclosed to the patient is a matter of medical judgment and stems from the doctor's general duty of care to the patient and not from the patient's right to be informed.

It should be noted, however, that the House of Lords modified this principle in some important respects. In particular the court enunciated its judicial right to intervene, if it comes to the conclusion that the disclosure of a particular risk is so obviously necessary to make a rational choice that no prudent doctor would omit to disclose. The court's proposition to modify the *Bolam* test has been said to be difficult to reconcile with the conclusion drawn by Dunn L.J in the Court of Appeal that the doctrine of informed consent is not part of English law.[61] Mason[62] suggested that it is not the

doctrine of informed consent which is not accepted in Britain. Rather it is "the doctrine of complete disclosure, particularly when based on the subjective patient [which] forms no part of [British] law."[63] He agrees with Robertson[64] who stressed the importance of the patient's comprehension as related to a full information disclosure principle. But in order to accommodate the American doctrine of informed consent with that which is developing in Britain, Mason suggested the abandonment of the term informed in favour of "rational", "reasoned" or "determinant" consent.[65]

NOTES:

1-Sidaway v.Bethlem Hospital Governors & Ors [1984] 1 All E.R 1018 (C.A), [1985] 1 All E.R 643 (H.L).

2-Chatterton v. Gerson [1981] 1 All E.R 257.

3-For further discussion, see Skegg, P.D.G., "A Justification For Medical Procedures Performed Without Consent", 90 L.Q.R (1974) p 512.

4-This principle has been applied, for example, in Cull v. Butler, 1 B.M.J 1195 (1932), in which a surgeon has been held liable for damages for having performed a hysterectomy instead of a curettage, the procedure that the patient consented to. Also in Hamilton v. Birmingham R.H.B, (1969) 2 B.M.J 456, a case concerned with the performance of a sterilization without the patient consent. See also, Devi v. Midland R.H.A, 7 Current Law 44 [1980].

5-See, for example, the B.M.A's HandBook of Medical Ethics (1980) para.1.8.

6-Chatterton v. Gerson [1981]1 All E.R 257.

7-At p 265.

8-Robertson, G., "Informed Consent To Medical Treatment", 90 L.Q.R 102 (1981) at p 113.

9-Hatcher v. Black, The Times, July 2nd 1954.

10-Bolam v. Friern H.M.C [1957] 2 All E.R 118.

11-The Times, July 2nd 1954.

12-Denning, L., The Discipline of Law, London, Butterworths 1979, p 244 in which the text of part of the judge's summing up is produced.

13-Robertson, op.cit, at p 115.

14-Bolam v. Friern [1957] 2 All E.R 118.

15-Per McNair, J at p 124.

16-Smith v. Auckland Hospital Board [1964] N.Z.L.R 241.SC, Revsd[1965] N.Z.L.R 191, N.Z., C.A.

17-Per Woodhouse J, [1964] N.Z.L.R 241 at p 250.

18-Chadwick v. Parsons [1971] 2 Lloyds Reps. 49.(Q.B); [1971] 2 Lloyds Reps. 322 (C.A).

19-Robertson, op.cit, p 115.

20-Hatcher v. Black, The Times July 2nd 1954.

21-Bolam v. Friern [1957] 2 All E.R 118.

22-O'Malley-Williams v. Broad of Governors of the National Hospital for Nervous Diseases [1975] 1 B.M.J, p 635.

23-It should be noted that this should not be taken to mean that failure to warn of a risk which is not remote can lead to negligence. British courts were still silent concerning this issue. See Roberton, loc.cit, p 116.

24-Chatterton v. Gerson [1981] 1 All E.R. 257.

25-Ibid at p 266.

26-See Brazier, M., "Informed Consent to Surgery", 19 Med. Sci.& Law 49 (1979) at p 53.

27-[1981]1 All E.R 257 at p 265.

28-Robertson, loc.cit, at p 117.

29-Chatterton v. Gerson, [1981] 1 All E.R 257.

30-Bolam v. Friern H.M.C [1957] 2 All E.R 118.

31-[1981]1 All E.R 257 at p 265.

32-Hills v. Potter [1983]3 All E.R 716.

33-Sankey v. Kensington and Chelsea Area Health Authority, unreported case, 2 April 1982, cited by Lewis, C.J "Medical Negligence: A Plaintiff Guide", Exeter, Wheaton & Co.Ltd., 1988, at p 204.

34-McLean, S.A.M., "Disclosure of Information, Consent to Medical

Treatment and the Law", Ph.D Thesis, Glasgow University, 1987, pp 312-13, also in her Book, "A Patient's Right to Know", Aldershot, Dartmouth Pub. Comp., 1989, at p 111.

35-Brazier, M., Medicine, Patients and the Law, Harmondsworth, Penguin Books, 1987, p 63.

36-Id.

37-see, for example, Gold V. Haringey H.A, The Times 17 June [1986], 1 F.L.R 125 [1987], Blyth v. Bloomsbury Health Authority , The Times, 24 May 1985 but reversed at time of going to press, The Times, 11 February [1987]

38-Sidaway v.Bethlem Hospital Governors & Ors 1 All E.R 1019 (C.A) [1984], 1 All E.R 643 (H.L) [1985].

39-Bolam v. Friern H.M.C 2 All E.R 118 [1957].

40-Sidaway v.Bethlem Hospital Governors & Ors 1 All E.R 643 [1985] per Lord Diplock at p 659.

41-Ibid at p 663.

42-1 All E.R 643 [1985] at pp 653.

43-Ibid p 653.

44-See Mason, J.K., & McCall Smith, R.A., Law and Medical Ethics, London, Butterworths, (2nd ed), 1987, p 157.

45-Supra.cit.

46-Gold V. Haringey H.A, supra.cit.

48-Ibid p 659.

49-Sidaway v.Bethlem Hospital Governors & Ors, supra.cit.

50-Bolam v. Friern H.M.C, supra.cit.

51-Kennedy challenged this argument as not being sufficient to reject the doctrine of informed consent in Britain, and pointed to the Canadian experience on the issue. He pointed out that the mal-practice crisis is not only due to the adoption of the doctrine of

informed consent, but also to other factors. See Kennedy, I "The Patient on the Clapham Omnibus" 47 M.L.R (1984) p 454, also updated and reproduced in his book, Treat me right, Oxford, Clarendon press, 1988, p 175.

52-[1984]1 All E.R 1018 at p 1030.

53-See pp 153-54, above.

54-Brazier, Medicine, Patients and the Law, op.cit, p 64.

55-Ibid.

56-Chatterton v. Gerson [1981] 1 All.E.R 257, Hills v. Potters [1983]3 All E.R 716, Sidaway v.Bethlem Hospital Governors & Ors [1984]1 All E.R 1019 (C.A), [1985] 1 All E.R 643 (H.L)

57-For a good discussion of the conceptual difficulties of consent based negligence, see McLean, S.A.M and McKay, A.J "Consent in Medical Practice" in McLean (ed) "Legal Issues in Medicine", Aldershot, Gower, 1981, P.96, also in her Book, A Patient's Right to Know, supra.cit, p 162.

58-[1981] 1 All.E.R 257 at p 265.

59-[1857] 1 W.L.R 582 at p 587.

60-Sidaway v.Bethlem Hospital Governors & Ors, supra.cit.

61-Mason, J.K., "Consent to Medical Treatment", (1986) Sco.L.A.G. p.73.

62-Ibid p 75.

63-Id.

64-Robertson, G., loc.cit, p.102.

65-Mason, loc.cit, p 76.

CHAPTER FIVE

THE PROBLEM OF HUMAN EXPERIMENTATION

The preceding chapters were concerned with the moral and legal requirements of obtaining the patient's valid consent in therapeutic treatment. It was argued that the physician is legally required to obtain the patient's valid consent prior to any intervention or administration of treatment. It was shown throughout the analysis of the development of the law of consent in the therapeutic setting that this legal requirement is basically designed to protect the patient's right to self-determination and to promote his or her individual autonomy. Courts have always relied upon, and invoked, this principle as the main justification for obtaining the patient's valid consent.[1] It was also argued that in order to be valid and therefore effective, the patient's consent must be competent, voluntary, and stem from a rational and intelligent decision made on the basis of a sufficient disclosure of information.[2]

In a similar fashion, the following chapters will deal with the requirement of seeking the subject's consent, whether they be patients or healthy volunteers, to human experimentation. It is submitted that the provision of a valid consent is as fundamental as it is in therapeutic treatments to the moral and legal validity of human experimentation. Hence, most laws governing the conduct of human experimentation, whether they be national or international, mention the necessity of obtaining the subject's freely given and informed consent as a primary condition that must be observed before investigators engage in biomedical research with human subjects. In

the experimental setting, obtaining the prospective subject's acquiescence serves a variety of purposes, ranging from promoting individual autonomy to involving the public in the research enterprise[3]. Moreover, Dyck and Richardson[4] argue that observance of the requirement of valid and informed consent also serves to maintain structural values, a type of moral value in addition to that of benefits, that morally justify the conducting of human experimentation. The use of human subjects in biomedical research may result in some risk to their physical and mental integrity, bearing in mind that they may or may not benefit from the knowledge gained from the experiments. In these circumstances, these subjects deserve respect and protection. Respect for them requires that they be treated as ends in themselves, not merely as means to an end. The legal requirement of obtaining valid consent is one way of ensuring that the will of another is respected and that the other is treated as an end and not simply as a means[5].

This is a simple statement about the necessity and importance of the subject's valid consent in biomedical research. The development of the law governing the issue will be discussed in the next chapter. Before that one will turn now to explore some conceptual and ethical questions raised by human experimentation.

5 : 1 DEFINITION:

For a definition of human experimentation or research involving human subjects, one would need to consider the concepts of "therapy" and "experimentation" or "research". This distinction is necessary to show which aspects of the law of valid consent might be applicable to the experimental setting, and which aspects might not.

It has been said that it is extremely difficult to distinguish between clinical research and the practice of good medicine, because stages of illness and individual people are so variable that every physician is carrying out a small research project when he or she diagnoses and treats a patient. Blumgart[6] for example, stated that "every time a physician administers a drug to a patient, he is in a sense performing an experiment"[7].

These statements might to some extent be true. Since individuals may react differently to the same treatment, the physician has to evaluate the patient's reactions to a medication, increase or lessen the dosage, or recommend another treatment within the limits, of course, that have been established by the standards of routine and accepted practice. Nevertheless, it should be remembered that the treatment in question has a statistically known probability of success, i,e., the treatment has been tested at some stages in the past for the first time. This is to say that treatments or therapies that are established as standards of routine and accepted practice are distinct from those which are still to be tested on human beings by the fact that the latter lack statistics about their probability of success. In addition, as will be seen below, the purpose of administering a therapeutic treatment is different from that of an experimental one, particularly in the case of non-therapeutic experiments. Accordingly, 'therapy' and 'experimentation' could be defined as follows;

(1) Therapy: in medical practice, the term therapy refers to certain procedures or activities undertaken solely to benefit or to enhance the well-being of an individual or all members of a group. The procedures and activities in question have already been subject to

investigation that determined their probabilities of success, after which they became the customary standard of routine and accepted practice. It necessarily follows that the customary standard of practice involves a reasonable expectation of success. The lack of precision on which to base such an expectation is not, however, sufficient ground to define the activities in question as research. As Levine[8] argued, uncertainty is inherent in therapeutic practice because of the variability of physiological and behavioural human response, and this kind of uncertainty is also, itself, routine and accepted. It is noteworthy that therapy can take different forms; it can be simply diagnostic or even preventive measures, or it may involve a treatment for a disease[9].

(2) Experimentation: To the contrary of "therapy", the terms "experimentation" or "research" involve the undertaking of scientific activities for the purpose of developing and contributing to general knowledge. As will be seen later in this discussion, the knowledge gained from experimentation may be of direct benefit to the patient/subject or/and to the patients of the future in the case of therapeutic experiments. In cases of non-therapeutic research, however, only future patients are likely to benefit from them.

Human experimentation, therefore could be defined as research or investigation that uses human beings as subjects[10]. It could also be defined, when contrasted to the concept of therapy, as the deviation from standard medical practice for the primary purpose of obtaining new knowledge[11]. For the purpose of this discussion, the use of the term experimentation or research will be taken to include all kinds of biomedical and behavioural research that come under the heading of human experimentation.

Before going any further, it is convenient at this stage to classify and clarify the different kinds of experimentation.

5 : 2 TYPES OF EXPERIMENTATION OR RESEARCH:

The classification of the different types of experiments that are performed on human beings is relevant to the determination of their ethical value. The most frequently cited classification in bioethical literature is the distinction between therapeutic experimentation and non-therapeutic experimentation.[12]

1-Therapeutic experimentation; resembles therapy to the extent that it is designed solely to benefit the patient/subject either to diagnose or to treat his or her illness. However, unlike therapy, therapeutic experimentation serves another purpose. In addition to its primary object of benefitting the patient/subject, the experiment is undertaken in a controlled way so that other patients can benefit from the knowledge gained from the study.

2-Non-therapeutic experimentation; by contrast, refers to an experiment designed neither to treat the patient's illness nor to enhance his or her well-being, but only to gain useful knowledge that can be used in the treatment of other patients either currently or in the future.

The Declaration of Helsinki[13] outlined a similar classification of human experiments. The Declaration distinguished between clinical research and non-clinical research:

> "in the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research,

the essential object of which is purely scientific and without direct diagnostic or therapeutic value to the person subjected to the research".[14]

1-Medical research combined with professional care: clinical research (section II title).

Clinical research is therapeutic research combined with professional care and carried out by the doctor treating the patient. The experiment must be related to the patient's illness and be designed solely to benefit that particular patient as opposed to being merely designed to gain new or useful knowledge.

2-Non-therapeutic biomedical research involving human subjects: non-clinical biomedical research (section III title).

Non-clinical research is neither therapeutic nor combined with professional care. It is carried out for the scientific purpose of seeking and advancing knowledge.

According to the Declaration, then, clinical research must be carried out on patients and must be research combined with professional care. The physician is allowed to subject his or her patient to an experiment provided that the experiment is likely to benefit the patient without undue risk. Naturally, the knowledge acquired from this experiment can be applied to other patients, but the doctor cannot subject his or her patient to an experiment solely to satisfy his or her personal curiosity, or to acquire knowledge. Para.II6 says;

"The doctor can combine medical research with professional care, the objective being the acquisition of new knowledge , only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient"

The Declaration refers to non-clinical research as "the purely scientific application of medical research carried out on human being"(para. III1). In determining the persons that can be subjected to non-clinical research the Declaration says;

> "The subjects should be volunteers-either healthy persons or patients for whom the experimental design is not related to the patient's illness." (para.III2).

Accordingly, the patient may be subjected to an experiment on condition that the experiment is not related to his or her illness and could not therefore benefit from the knowledge that can be acquired from it. This principle can not be easily reconciled with the former principle developed in para. II6. Belsey[15] and Levine[16] remarked on this inconsistency between these two principles. Belsey argued that this inconsistency can be solved only by distinguishing the patient's own doctor and other doctors[17]. When the experiment is combined with professional care, this experiment would have to be carried out by the physician treating the patient. But when the research is purely scientific it would have to be performed by another doctor who is not treating the patient. Belsey concluded that the Declaration impliedly allowed the use of patients in non clinical research on condition that the experiment is carried out by other than the patient's own physician.

In not permitting the physician to experiment on the patient whom he or she is treating, the Declaration reasoned that because of his or her illness and complete dependence on the physician, the patient can not properly give an informed consent to the proposed experiment. Therefore "the informed consent should be obtained by a doctor who is not engaged in the investigation and who is completely independent of

this official relationship" (para. I.10.). Belsey has also challenged this recommendation[18]. He pointed out that the patient, particularly a hospital patient, is unlikely to disappoint any doctor who approaches him or her and asks for participation in an experiment because such a patient may feel that he or she is dependent on the whole staff of the hospital and not only on his or her personal physician.

This is to say that the distinction implicit in the Declaration between the patient's own doctor and other doctors is irrelevant, because in hospital, the patient is in the care, and under the responsibility, of the community of doctors and not only in the care of his or her own doctor, a fact that the Declaration failed to recognize as Belsey[19] pointed out. Two conclusions can be drawn from this misinterpretation of the real nature of the doctor/patient relationship in hospitals;

1- The Declaration's objective of obtaining the patient's consent without duress can not be attained by merely shifting the task of soliciting the patient's consent to an experiment to another doctor.

2- The idea that the hospital patient can only be subjected to non-clinical research by other than the patient's own doctor becomes doubtful[20] or meaningless.

The classification of the different types of experiments between therapeutic and non-therapeutic or clinical and non-clinical research has also been challenged as being unable to include all types of experiments. It has been argued that there are some types of experiments that can not be clearly identified as either therapeutic or non-therapeutic. For example, experiments designed to explore the cause of a disease can be put on the borderline between clinical and non-clinical research. The patient may or may not benefit from the

experiment depending on the circumstances[21]. Moreover, there exists a kind of medical experimentation which has both therapeutic and non-therapeutic aspects. This is called mixed therapeutic and non-therapeutic experimentation. Perhaps one of the most problematic examples of mixed experiments is the Randomized Clinical Trial, (R.C.T)[22] which will be returned to later in this discussion. Because of the problems that derive from the use of the distinction between therapeutic and non-therapeutic research, some scholars have advocated[23]the abandonment of this classification. Others have noted,[24] however, that there are also strong arguments for retaining this distinction. It is important, says Verga[25], for the determination of the ethical value of an experiment to know whether or not the project is designed to benefit the subject, and this fact can easily be identified or inferred from the purpose of the experiment being either clinical or non-clinical.

3-RANDOMIZED CLINICAL TRIALS (R.C.Ts)

It has already been mentioned that there exists a kind of experiment which has both therapeutic and non-therapeutic aspects. The subject in this type of experiment, usually a patient, is receiving medication for a particular illness. The way the treatment is being administered however, is not chosen with the sole objective of relieving or curing the particular patient of his or her illness. Rather the treatment is administered as part of an experiment designed to test new therapies or to compare the efficacy of various established treatments. It should also be mentioned that the purpose of this study is not limited to reporting the results of different treatments in particular cases. Rather, different therapies are tried, and patients are assigned to treatment categories partially

according to the needs of the research design. Usually, this kind of experiment takes place in order to decide whether a new drug or other treatment is better than a conventional one, or none at all. The randomized clinical trial is but one example of this kind of experiment in which patients suffering from the same illness, or healthy volunteers, are divided into groups and subjected to different therapies[26]. The R.T.C is usually carried out in either of two ways; (1) one group will be treated according to the conventional therapy(control group), whereas the other group will receive the experimental treatment(experimental group). (2) One group will receive a new drug and the other a placebo.

Many points have been noted against R.C.Ts[27]. It has been pointed out for example, that while the control group could be denied a chance of receiving a better therapy, the experimental group could be subjected to the risk of harm by the therapy under investigation.[28] The assumption is that in a controlled trial, a serious effort is made to cure all patients. The ethical question, however, is not whether the patient will be completely cured, but rather whether "- unrestrained by the [therapeutic] trial design - the patient could have been treated more efficiently"[29]. This question is essentially related to the design of the trial. The trial must be designed in such a way as to ensure that its objective be attained as rapidly as possible.[30] Some physicians argue however, that the alternative therapies between which patients are randomized both have a great deal to recommend them and therefore, there is no real sense in which one or the other group is being deliberately disadvantaged.[31]

The controlled trial is also characterized by its double blind technique and randomization. These are of major importance for the

success of the trial. The double blind technique for example, is necessary for the evaluation of the new or already established drugs. It is believed that the physician is unlikely not to have a certain preference in a choice of treatments. This technique serves to eliminate such subjective influences by leaving both the doctor and the patient uninformed as to the identity of the drug which is being used[32].The second principle, randomization, is basically implemented to exclude, as Helmchem and Müller-Oerlinghausen[33] put it,"unknown objective influences".

The idea of having a truly randomized trial remains, however, difficult to achieve[34]. In many R.C.Ts, randomization involves some form of pre-selection. For example, volunteers for trials distinguish themselves from those who are not[35]. In other instances, some patients may be deliberately excluded from the controlled trial because of the severity of their diseases[36]. As a result, the trial is limited to evaluating the effectiveness of the therapy for only the milder forms of illness. This selection of patients may also make it difficult to find a more effective treatment for the most severely ill patients. Nevertheless, randomization in controlled trials is still one of the major issues in clinical investigations and particularly in therapeutic trials for cancer. In this respect, many physicians, especially those involved in the primary care of patients, have been hesitant to enroll their patients in R.C.Ts. Many of them pointed to the tension they felt between their role as researchers committed to the success of the trial and their role as doctors committed to their patients' well-being. The enrollment of patients in R.C.Ts, they argue, may jeopardize the doctor/patient relationship[37]. Moreover, problems may also arise in respect of the legal requirement of obtaining the patient's consent to participate in an R.C.T. The

assumption is that no randomized clinical trial can be ethically valid unless physicians have a genuine doubt as to which therapy yields the best outcomes[38]. In such circumstances, it is undoubtedly difficult for any physician to ask his or her patient to take part in a trial without being able to specify which treatment will be administered. This may lead to the confusion of the patient and even end up with a refusal. These cumulative adverse factors are very often the cause of the slow accrual of patients to important R.C.Ts[39].

It is noteworthy that during the last few years a modification has been introduced to the technique of randomization. The new procedure, one of those suggested by Zelen[40], involves some form of pre-selection or pre-randomization before discussing the treatment with the patient and obtaining his or her consent to take part in the study. In this respect, it has been pointed out that if the randomization procedure is made much more comfortable for the physicians, more patients would be approached to participate in R.C.Ts and that more patients would be encouraged to agree to participate if they were informed of their assigned treatment[41].

The pre-randomization technique may obviate the difficulties encountered in the accrual of patients, but it may also give rise to other ethical and practical problems[42]. As has been said;

> "....it seems doubtfully moral to use what is essentially a ruse in order to obviate agreed ethical practice which is, in addition, an integral part of the basic principles of the Declaration of Helsinki."[43]

This is to say that the search for the appropriate procedure for the evaluation of alternative treatments, must take into consideration the care due to patients. If this commitment to present patients is

attenuated in favour of benefits to those of the future, the implicit assumptions of the doctor/patient relationship are violated.[44].

5:3 THE MORAL JUSTIFICATION OF HUMAN RESEARCH:

It has been said that the use of human subjects in clinical research is not only morally accepted, but in certain instances, morally required. This conclusion is drawn from two types of considerations; the limitations of experimentation with animals, and the moral requirement of alleviating human suffering.[45]

With respect to the former, it has been scientifically proved that because of species-specificity, different species have different chemical reactions[46]. Therefore, in order to establish sound medical practice, medical research has to rely upon the knowledge gathered from the reactions of human subjects themselves. Moreover, even if such differences do not exist, there always comes a time at which the treatment has to be evaluated in the human being. As Marston pointed out;

> "Even when the situation is as clearcut as it was when it became possible to prevent the death of experimentally infected mice by treatment with Penicillin, it still was necessary to test the antibiotic in man."[47]

In addition, there is always the need to evaluate in humans different therapies that are already in use. As Marston[48] noted, the therapeutic value of many reputed therapies is in fact unknown. It is necessary therefore, he recommends, that controlled studies be carried out to establish their relative effectiveness. The well being and health of all human beings depend upon continuing research in man. As has been said; "The proper study of mankind is man."[49]

Concerning the second ground that justifies the conducting of human experimentation, it has been claimed that the submission of human subjects to many kinds of experiments, though they involve real risks to them, is justified by the very great benefits that can be gleaned from their results, either to present patients or to those of the future. A good illustration is the development and use of vaccines. Although the use of vaccines is known to have a statistically minimal, though real, risk to their recipients, they have been tested on human subjects and then became compulsory or highly recommended treatments, designed to prevent disease. This is said to show that in instances where a serious harm needs to be prevented, the use of human subjects in risky experiments can be easily justified and is more likely to be considered as morally required[50].

What has been said so far should not be taken to mean, however, that the justification covers only experiments related to instances in which the human being's existence is at stake. Rather, even those experiments which are carried out for the sake of increasing the pleasure and enhancing the well-being of all human beings, can be morally justified in certain instances. What is important, in fact, in the evaluation of any research project, is the assessment of the possible harm such an experiment may cause to the human subject as well as the assessment of all its potential benefits. Usually, in order to be ethically justified, the benefits occurring from the results of the experiment must more than offset all its potential associated risks. Considered from another point of view, the subject's interests in not being harmed either physically or mentally, should prevail over the community's interests in acquiring new knowledge.

To summarize briefly the points made so far, it can be said that human experimentation is valued because, even with the use of animals, the human being remains the appropriate subject of medical research for the establishment of sound medical practice. Experimentation is also necessary for the advance of scientific knowledge which leads in itself to the promotion of health (utilitarian argument).

It is noteworthy that human experimentation has been also justified on deontological grounds and by invoking the principle of justice[51]. According to this view, every person currently alive benefits in one way or another from past human experimentation. In other words, the submission of past human subjects to various controlled studies of, for example, vaccines and antibiotics has contributed to the well-being of all humans. Therefore the principle of justice requires that present human beings contribute, in a reciprocal way, to the alleviation and eradication of human suffering. In this respect McCance[52] emphasized the importance of impressing patients with the facts that hospitals undertake experimental work, not only for the immediate benefit of the ill, but also for the benefit of mankind, and that the patients themselves owe incalculable advantages to previous experimentation that has been carried out on others.

In his leading article "Philosophical Reflections on Experimenting with Human Subjects" Jonas[53] challenged both of these proposed justifications of human experimentation.

First of all, Jonas rejects the argument that participation in human experimentation by beneficiaries of previous research is a moral duty required by the principle of justice. He argues that both experimenters and subjects of the past engaged on experimentation voluntarily and freely as acts of altruism and moral heroism.[54] All

that present humans owe to the past as debt, if there is any, is a debt of gratitude to the previous generations for their contributions to the alleviation of human suffering, but not an obligation to society based on the principle of justice. Jonas' rejection of the justice argument is based upon the idea that human experimentation is, in most cases, an optional rather than a vital human activity.

With respect to the utilitarian argument, while recognizing that human experimentation is a major scientific method for advancing scientific knowledge, Jonas reiterates the view that most research involving human subjects is not vital to the well-being or survival of the human species[55]. He argues that medical progress is "an optional goal, not an unconditional commitment"[56] This reasoning led him to conclude that only a present threat or as he says a "clear and present danger", or a "state of emergency"[57] would provide a sufficient justification for human experimentation.

Schafer[58]noted that according to Jonas' reasoning, the social misfortune of those potential victims of disease whose suffering could be alleviated by continuing medical research, is not a sufficient ground to expose human beings to the risks of experimentation. This view suggests that mere benefits, however great they may be, can not justify human experimentation, but exceptionally, a state of national health emergency can. Jonas' position on the justification of human experimentation is based upon the principle that individual human rights e.g., the right to be free from invasion of one's bodily integrity and the right to consent, are supremely important. It is this primary commitment to protecting the rights, dignity and inviolability of the individual which makes Jonas unwilling to accept "benefits" as a sufficient justification for human experimentation. As it has been said the adoption of Jonas' view would require the

virtual cessation of experimentation with human subjects.[59]

Undoubtedly, such an approach would deprive society of the benefits of new remedies as well as of an important scientific method for striving against existing and threatening diseases. Moreover, it could also be argued that there is a significant ethical cost attached to not continuing medical research. In highlighting this point, Dr George James[60]stressed the need to consider the rights of other generations to benefits from the results of medical research. He says:

> "In the discussion of ethical considerations relating to clinical research the rights of the unborn generations to benefit from the fruit of research must also be weighed. It can be debated that no man today has the free and the moral right to condemn his grand children to the same perils to which he is exposed by virtue of the present lack of effective scientific information, and his failure to participate in a search for it"[61]

Experiments which are designed to evaluate the effectiveness of new and already established medical products are instances in which it is, and will always be, necessary to use human subjects. To forego such experiments, is to expose many persons to the risks of injury associated with the use of insufficiently tested remedies either old or new. On the other hand, since, as mentioned earlier, there would be limited value in therapies that have been tested only on animals, it is clear that human experimentation will continue to be necessary as long as drugs continue to be developed. Therefore, progress in drug treatment is dependent upon the continuation of human medical research.[62]

It is convenient to note at this stage that international agreements, e.g., the Declaration of Helsinki[63], tacitly allow the

continuation of medical research. Such position evidences that

> "both the international community and medicine itself see a need for such experiments as a contribution to the development of patient care and the wider interests of medical science"[64]

This commitment is grounded upon the assumption that medical progress will improve the well-being of present patients or those of the future.

A total commitment to medical advancement is not flawless, however. Many assume, for example, that every piece of acquired medical knowledge leads necessarily to the improvement of health care. This is not always the case. As McLean and Maher[65] remarked "much research is repetitive" and generated, to some extent, by motives other than patient care, for example, "the exploration of scientific hypotheses or the profitability of the pharmaceutical industry."[66] In such cases a reduction in the number and scope of medical investigations is suggested as a measure to diminish the risks of harm to which human subjects are exposed.[67] Moreover, it will also be necessary to introduce some form of scrutiny to ensure that human subjects are not exploited under the pretext of medical progress. This is related to the issue of social control, an issue which will be considered later in this discussion.

Given the fact that human experimentation remains the only appropriate method for the acquisition of new knowledge, the question which should be dealt with is not whether the use of human subjects could ever be justified. Rather the question is related to the conditions under which such use could be tolerated in experiments that involve some risks of harm to human subjects. Most of these conditions were mentioned in the international codes of ethics, such

as the Declaration of Helsinki, in relation to the ethical framework within which human experimentation should be carried out.

Two crucial conditions, in particular, must be satisfied to justify the use of human subjects in experiments that are of some risk to their bodily and mental integrity;

1-The experiment should anticipate specific benefits accruing from its result. In other words, the experiment must be aimed at patient care or/and at the acquisition of new knowledge(with the former predominating)[68]. It also should be carried out on the basis of sound scientific hypotheses tested in the laboratory and on animals.[69]

2-The experiment should be carried out only with the freely obtained informed consent of the subject.[70]

It should be noted that these two conditions had also been emphasized by many philosophers. In stressing the need to observe the requirement of obtaining the subject's valid consent, Dyck and Richardson[71],for example, noted that it is the observance of the requirement of consent which makes all potential benefits meaningful. They argue that although there are harms that can be balanced against benefits in the matter of deciding which risk is morally justifiable, there is a kind of harm which can not be outweighed by any benefit however great that benefit may be. This harm is to the "violation of a structural value"[72]that necessarily results from the violation of the requirement of obtaining the prospective subject's informed consent. Such harm can not be tolerated since these values maintain the social systems. Among the inviolable structural values that the requirement of informed consent protects, they mentioned "veracity, freedom and justice."[73]

5:4 CONSENT TO HUMAN EXPERIMENTATION:

According to what has been said so far, it is clear that an ethical and legal experiment depends, in part, upon free and autonomous participation by the subject and this, in turn, depends upon valid and informed consent, the nature of which has been discussed in the previous chapter.

In human experimentation, the need to observe the requirement of informed and valid consent is even greater than in the sphere of pure patient management. An excessive zeal for medical advancement may jeopardize, for example, the subject's rights to autonomy and self-determination. His or her freely obtained acquiescence is a way of protecting these fundamental rights. Moreover, as in therapy, the provision of consent is also crucial for the validation of the interaction[74].

Generally, most aspects of the law of consent in therapeutic treatments might be applicable to human experimentation. Nevertheless, it should be noted that the experimental nature of the procedure gives rise to acute problems in respect of the application of the requirement of informed consent. Each component of the concept raises its own issues. The information aspect, for example, may be questionable in terms of the amount of information disclosure or/and in terms of its assimilation on the part of the prospective subjects. On the other hand, the component of consent may become ineffective if the decision to take part in a given experiment is granted otherwise than freely and voluntarily.

It has been said that, although international agreements made it clear that the subject's consent must be voluntary and informed in nature, and although individual doctors may strive for the realization of such an objective, the subject's consent "can never be fully

informed in experimental procedures since ex hypothesi the nature and extent of the risk is unknown."[75] In such cases the patient's acquiescence does not cover "the nature of the risk" which may materialize, but merely "an incalculable risk worked out on predictions based on pre-existing knowledge or experience"[76].

With respect to the voluntariness aspect of the subject's consent to experimentation, it is not possible to assert with certainty that his or her consent is always freely granted. This could particularly be true in respect of clinical research where the patient has a self-interest in the cure. A hopelessly ill person, for example is unlikely not to agree to a proposed procedure that may have a possibility of bringing an end to his or her suffering.

It could be argued, however, that the self-interest aspect which characterizes the hopelessly ill patient's decision to participate, does not affect his or her decision and successively his or her consent. Furthermore, still in respect of the hopelessly ill patient, it would probably be difficult to reconcile the act of interfering with the patient's choice to take his or her chances in an experimental procedure with the extreme position society has on the rights of the individual.

The human subject's consent, in particular to non-clinical research, may also be questionable, not in the sense of not being fully informed, since even in such case "the general good of experimentation overrides the diminution in the right to receive information which the [subject] could otherwise claim."[77] That is to say that the subject's consent could be informed in the sense that he or she knows that the experimental intervention involves, by nature, known and unknown risks. If one considers the argument that it is not rational to accept unknown risks in the knowledge that they

are of no benefit, the subject's decision to participate in a non-therapeutic experiment would be irrational, and therefore paternalistic interference would be necessary. If, however, the decision to take part in this kind of experiment is based on the principle of acting and living for the interests of others, such a decision would be rational. For since altruism is morally good, acting on the basis of such a principle is not only morally acceptable but also rational.

Nevertheless this does not, in any way, remove the fundamental problems associated with the provision of consent to human experiments since the need to provide the subject with a maximum disclosure of information relating to the risks and benefits of the experiment remains important regardless of the motives on which the subject based his or her decision to participate in experiments(self-interest or altruism).

Generally, the subject's consent to a research project must be preceded by four types of explanation; the purpose of the research, the benefits to the patient and society, the risks associated with the performance of the experiment and the alternatives. In Halushka v. University of Sackatchewan [77],the court stated: "there could be no exceptions to the ordinary requirements of disclosure in the case of research as there may well be in ordinary medical practice."[78] That is that in the experimental setting, and particularly in non-therapeutic experiments, a more detailed disclosure and no therapeutic privilege should be the rule, since the subject will not benefit from the results of the research on the one hand, and there is no need to balance the the probable effect of lack of treatment against the risks involved in the proposed procedure on the other.

More acute difficulties can be faced when obtaining the subject's

informed consent to participate in R.C.Ts. As mentioned earlier, it is necessary for the success of a controlled study that it be carried out with some measure of ignorance-randomization or pre-randomization and the double blind technique.[79]

It is clear that it is difficult to satisfy the requirement of informed consent in such circumstances since the subject will be denied any information relating to the fact of randomization or to the treatment that will be administered. Even the pre-randomization technique has its own ethical problem. Proponents of the pre-randomization technique argue that since the patient in most cases aims to receive the best standard therapy, it will not be necessary to seek the informed consent of the control group(the group of patients that will receive the standard therapy in a controlled study). Only the experimental group(the group that will be treated with the experimental or new therapy), they argue, would learn that they are enrolled in a controlled study.[80]

The main point that has been noted against this technique questioned the ethical and legal validity of an R.C.T that leaves half the patients uninformed of the fact that they were study patients. This is to say that the pre-randomization technique also involves a violation of the rights of one group of patients(the control group), by subjecting them to a controlled study without their knowledge and acquiescence.

The complications relating to obtaining the subject's consent to R.C.Ts are such that many laws, e.g., Swedish law[81], mentioned the legal obligation to seek the subject's informed consent but did not define the extent of the information that must be disclosed. In the U.S.A, some states' statutes lay down the information that must be given to patients in certain treatments.[82] In the U.K, particularly

in respect of cancer therapies, the leading authority on cancer trials, the Cancer Research Campaign Working Party in Breast Conservation (the Working Party)[83], recommends the obtaining of the subjects' informed consent in major multicentre research programmes. It has been said, however, that "the issue of informed consent remains unresolved [in the U.K.]."[84] It has also been noted that "It is intolerable...that the burden of accountability should be placed entirely on [the] doctors concerned"[85]. In this respect, the Working Party suggested the formulation of a workable code of conduct for all clinical trials[86]. The Working Party reasoned that the difficulties currently faced may nullify the R.C.T which is a major scientific method for the evaluation of new therapies,"taking [medicine] back into the dark ages where therapeutic innovations were judged by intuition and wishful thinking."[87]

Further problems associated with the provision of consent relate to the difficulties that the subject may face in comprehending all the complexities of the subject. In this respect a leading article in the Lancet[88], noted that the patient should not be included in the trial if he or she is not capable of assimilating the basic plan of management.

Most scholars think, however, that the complexities of the issue are such that the ideal informed consent in these circumstances can only be rendered by those involved in the caring profession.[89]

A-EXPERIMENTATION AND PRISONERS:

It is obvious that prisoners as a group do not differ physically from other adults. Nor is there any difference between them and other adults in the capacity to comprehend an explanation of proposed research. Thus it is not usually alleged that prisoners are less able

to assimilate the risks, discomforts and benefits that may be the result of experimentation than free-living individuals. Rather it is often claimed that prisoners cannot render an informed and valid consent because of the fact of their incarceration.[90]

Proponents of research involving prisoners argue that such research could be beneficial both to prisoners and to society. It has been said, for example, that participation in experiments improves the self-image of many prisoners. At the same time, their involvement in various types of non-clinical research, e.g., the early phases of drug testing, contributes to the general welfare of society.[91] On the other hand, the circumstances in prisons make these institutions the ideal places to carry out experiments. Life is routine and subject to few variations. The population is relatively stable which makes long range studies feasible. And it is less expensive to use prisoners than it would be to use other subject groups.

The main question that the use of prisoners in research gives rise to is whether prisoners are capable of providing an informed consent.

Objectors to the use of prisoners in experimentation argue that because of the very nature of their incarceration, prisoners do not have a real freedom of choice in respect of their participation in these activities. Coercion may take different forms; payment, a reduced sentence or a few weeks in hospital. In short, their self-interest may influence their decision to take part in experimentation. This concern is articulated in the Nuremberg Code[92], Para.I reads;

> "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent, should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over reaching or other ulterior form of constraint or coercion, and

should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." (emphasis added)

It is obvious that the situation of prisoners is not really one in which an individual can exercise free power of choice. 'Self-interest' is surely an element which may affect the subject's decision.

It is argued, however, that 'self-interest' does not in itself invalidate the prisoner's consent to take part in research, since consent is always speculative in experimental cases.[93] Moreover, 'self-interest' is, in fact, a characteristic of any voluntary participation. Thus, it is rather the combination of self-interest and their vulnerability to exploitation which makes prisoners unsuitable as subjects for human research. The prisoner, for example, may be subjected several times to experimentation with his or her free will without being aware of the risks involved in such practices or their long-term effects. This consideration is the basis of the legal or moral exclusion of certain groups of subjects (prisoners, children and the insane) from non-clinical research. As has been said, "[t]he vulnerability of those groups makes control over experimental procedures imperative."[94]

5:5 SOCIAL CONTROL:

The issue of social control over experimentation raises procedural rather than substantive questions. The various alternative mechanisms of social control are established as a means for ensuring that human research is carried out with the observance of basic ethical and legal principles and requirements.

A-The Need to Control Human Experiments:

Two considerations, in particular, require the establishment of such control. First of all, there is the need to protect the human subject's mental and bodily integrity. This protection requires that a reliable form of scrutiny be introduced to maintain the balance between the interests of medical advancement and the well-being of the human subject. Second, human experimentation is basically meant to promote public health, i.e., to serve the interests of society. This factor dictates that society itself intervenes and controls the conduct of human experimentation as a means of ensuring that it serves its perceived interests on different levels.

The existence of such control is important if one considers the fact that international agreements relating to the conduct of human experimentation have been laid down in protest at what human subjects had been subjected to in the past and particularly at the atrocities committed by Nazi doctors during the Second World War.[95]

Social control is also necessary to prevent the exploitation of vulnerable subjects (children, prisoners and the chronically or terminally ill patients). A good illustration of how the vulnerable can be exploited is the injecting of chronically ill patients with live cancer cells, a case known as the Jewish Chronic Disease Hospital.[96]

Furthermore, such control whether it be national or international also serves a symbolic purpose which consists in reminding the investigator to consider deeply the ethical and legal validity of his or her project before engaging in human experimentation.

B-Mechanisms of Control:

The conduct of human experimentation is usually controlled and monitored by both international and national laws.

At the International Level:

With respect to international scrutiny, it has been pointed out that although international law is an inefficient means of controlling professional practice, the international community's codes of ethics remain a valuable statement of the purpose and boundaries that should be observed by all those involved in biomedical research.[97] The inefficiency of international law stems from the fact that few sanctions usually follow its breach. As a result, the contemporary medical enterprise still continues to provide examples of unnecessary and unethically conducted experiments.[98]

The provision of these codes, particularly those relating to the issue of consent will be examined in the next chapter, but it is worth noting at this stage that further efforts are still being made by international organizations to discuss the ethical issues arising from contemporary medical science and technology, and to issue recommendations and resolutions relating to questions of law, human rights and safety. In this respect the Division of Science and Technology Policies, as part of the United Nations Educational Scientific and Cultural Organization (U.N.E.S.C.O), organized many conferences and symposia on the ethics of human research in Western Europe in the period between September 88 and May 89. Most of the documents which were presented examined the ethics of the use of human beings and embryos in medical research, organ transplantation, genetic engineering and artificial insemination.[99] Among the important documents which were adopted during these sessions is Resolution A.2-

78/88 adopted on Sept.88 on European Harmonization of Medicoethical Questions. It was noted that "the European Code (of Ethics for the Medical Profession) does not necessarily reflect the medicoethical views of the health care sector as a whole or of all sections of society."[100] In addition, doubts have been expressed as to whether the code in question is fully representative of the views of the medical profession in all the European states concerned. Accordingly, the European Parliament recommended that ethical committees in every member state at various levels be made up of equal numbers of men and women,[101]the constitution of a European Ethical Committee for coordinating the national ethical committees,[102] and called for these committees "to be constituted so as to garantee adequate representation of all the parties concerned in the health sector..."[103]. Among the other documents which were adopted are two resolutions. One on the Ethics and Legal Problems of Genetic Engineering,[104] and the other on Artificial Insemination 'In Vivo' and 'In Vitro'.[105]

The main purpose of these documents is to unify the general ethical principles governing the medical enterprise in Europe as complementary documents to those adopted at world level. On the other hand, these can be of great assistance to individual states in Europe or elsewhere in their effort to regulate by way of legislation the medical profession in general and the research enterprise in particular.

At National Level:

In effect, different checks at national level have been developed to scrutinize and monitor experimentation.

Some noted, however, that given the very confidential nature of medical transactions, these controls are, to some great extent,

"medicine dominated, relying heavily on the evidence and opinions of the colleagues of the researchers."[106] It necessarily follows that such controls may be established according to a "purely or substantially" medical view of the ethics of experimentation neglecting thereby "the competing claims of community based morality or perception."[107]

In the U.S.A, since 1966 the National Institute of Health, Food and Drug Administration(N.I.H.F.D.A) and the Department of Health, Education and Welfare(D.H.E.W), have issued increasingly detailed regulations governing the use of human subjects in medical research. This was followed by the establishment of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (N.C.P.H.S.B.B.R) in 1974, which was designed to advise the D.H.E.W.[108]

Part of the 1966 D.H.E.W guidelines included a decision to decentralize the review process. Institutions receiving federal funds were urged to establish Institutional Review Boards(I.R.B) to undertake research review. Their role is to ensure that research projects are designed in accordance with the federal regulations. Many substantive requirements must be satisfied: the research project must, for example, minimize risk to human subjects; the risk must be reasonable in relation to the potential benefits; informed consent must be obtained and so-called vulnerable subjects must be protected from undue coercion.[109]

Like the U.S.A, Britain has also developed several layers of scrutiny to control the conduct of human experimentation. The common law is still considered as a major means of controlling the potential abuse of clinical freedom. The physical touching of an individual without his or her consent may be actionable as an assault and battery

even though there is no physical injury; physical touching of a subject or the manipulation of his or her conduct by misrepresentation or breach of a fiduciary relationship is actionable as fraud; and the careless conduct of an experiment is actionable as negligence if the subject suffered injury.[110]

In addition to these doctrines of the common law, further mechanisms of control have been introduced, in particular, in respect of the marketing of new pharmaceutical products, namely the establishment of the Committee on Safety of Medicines[111]as a result of the Medicines Act 1968. The role of this organization is to ensure that no new pharmaceutical product will be in use before its scientific hypotheses have been tested in the laboratory and on animals. Further investigations or evaluations of the new products on human beings will then be authorized under close supervision.

It is convenient to mention in this respect that many recommendations have been issued by the Royal College of Physicians (Working Party) relating to the use of volunteers in such investigations,[112] as well as recommendations regarding the kind of relationship that must be kept between physicians and the pharmaceutical indistry.[113] The Working Party acknowledged, in particular, the need to have a close and constructive relationship between the medical profession, which prescribes drugs and the pharmaceutical industry, which produces and markets them. It was recommended, however, that such relationship be conducted on strictly professional lines and neither party should abuse its position for financial or other gain or mislead the other as to factual evidence about the drug under trial.[114]

A further layer of scrutiny was developed on a recommendation of the Medical Research Council by means of the institution of Research

Ethical Committees in all hospitals engaging in experimental work.[115] Although these committees are constituted mainly of members from the medical profession, they provide, as has been pointed out, a model for co-operation between the medical enterprise and the public.[116]

It should be noted, however, that these committees are still uncertain "whether their role is purely advisory or whether they are responsible for monitoring research in progress as well."[117] Some scholars relate this uncertainty to an inherent ambiguity in the original Medical Research Council guidelines and the statement by the Royal College of Physicians in London.[118] On the other hand there are still doubts as to their efficiency in scrutinizing research projects. Most critics, for example, pointed to the lack of debate on general principles that govern the use of human subjects, and the degree to which doctors manipulate ethical committees.[119] There are many examples in which trials have proved very harmful, if not fatal, although sanctioned by many ethical committees.[120]

In any event, although the function of these committees does not constitute the ultimate means of controlling human experimentation, their existence is necessary to keep a contact between the experimental enterprise and the public.

5 : 6 CONCLUSIONS:

The main issue that the present chapter has discussed is the conditions under which it would be justifiable to subject human beings to experimentation when such subjection will be likely to harm them. As has been shown above, two considerations of major importance must be satisfied to justify the use of humans in risky experiments; the

anticipation of benefits from the conduct of such experiments and the observance of the legal and ethical requirement of obtaining the subject's informed and valid consent.

That is, the fundamentally crucial aspect of all experimentation is the right of the human subject whether he/she be patient or volunteer to make informed and rational decisions about his or her own body. As has been said, the investigator's role is secondary to the interest that the human subject has in his or her own autonomy.[121] The subject's decision to take part in experimentation can be motivated by a self-interest in the cure or by altruism, but still remains a rational decision.

Whatever the subject's motives, however, his or her interest in not being harmed as a result of experimentation must prevail over the interest of the community as a whole in acquiring new knowledge or developing new therapies. In other words a balance is necessary that allows for the continuation of all types of experiments which are likely to benefit society without neglecting the basic human rights of the individual subject.

This is related, in part, to the design of the experiment. The research project must be designed in such a way as to ensure that the subject is exposed to minimum risks, and that the experimentation is not carried out unless there is a real need to investigate or evaluate new or old therapies or techniques. In this respect, some scholars have pointed out that the doctor/investigator "should be entrusted with the duty of himself deciding when a medical care measure needs to be evaluated from an ethical viewpoint."[122] It is argued, however, that the adoption of such a view, places the physician in a powerful position, and requires a reduction of the rights of the subject "whose interests have already been subverted to some extent, even in therapeutic experiments, by the lack of available information."[123]

It would be safer to say that since many experiments may or do benefit the community, it is admittedly necessary that human experimentation continues. One way of ensuring its fruitful continuation is the introduction of an efficient system of control. Such controls can be of great help in accommodatimg the conflicting interests of all those involved in human research - the interests of the subject in the integrity of his or her personality and physical well-being; the interests of the investigator in pursuing his or her vocation; the interests of the community in acquiring new knowledge, particularly knowledge bearing upon public and individual health. Moreover, these controls can afford a reduced but adequate protection to vulnerable human subjects when experimentation has to be carried out on the otherwise vulnerable. Children, for example, may be needed to be used as subjects in certain experiments that deal with specific diseases that affect only children.[124] In such cases special attention is needed in the assessment of the risks and benefits associated with the performance of these experiments, particularly, non-therapeutic ones.

The question that can be asked now is whether the present mechanisms of control, including the law's response to the issue, are efficient enough to keep experimentation going fruitfully without subverting the interests of any of the parties involved.

At present it is the medical profession in the U.K. which is in charge of the control of human research. Although the function and constitution of Research Ethical Committees has been criticised, their existence is said to be necessary to keep a contact between the experimental enterprise and the public. In this respect, a review of the constitution and function of R.E.C.s and the adoption of a policy which allows for higher percentage of lay membership in R.E.C.s are

recommended.

The law's intervention, on the other hand, is limited to a few fields of experimentation. It seems that it is only in relation to research with new drugs that there is specific legislation. More specific legislation, in particular, must be promulgated. In this respect it is suggested that such legislative regulation can take the form of an enforceable legal framework that defines the general principles and guidelines laid down by the international community in the Declaration of Helsinki,[125] and other international agreements.

Consent to medical research, in particular, may be very problematic as was shown above, and surely all of its principles deserve a proper definition. But before making any speculation, it is useful first to outline the development of the law governing consent in the experimental setting including its current status.

NOTES:

1-See chapter three supra.

2-See chapter two supra.

3-Katz, J. & Capron, A.M., Catastrophic Diseases: Who Decides What? New York, Russell Sage Foundation, 1975, pp.82-90.

4-Dyck, A.J., and Richardson, R., "The Moral Justification for Research Using human Subjects" in Humber, J.M., and Almeder, R.E., (eds), Biomedical Ethics and the Law, N.Y and London, Plenum Press, 1976, pp. 244-45.

5-Macklin, R. and Sherwin, S., "Experimenting on Human Subjects: Philosophical Perspectives", 25(3) Case Western Law Rev., (Spring 1975) p 434.

6-Blumgart, H.L., "The Legal Framework for Viewing the Problem of Human Experimentation", in Freund, P.A. (ed) :"Experimentation with Human Subjects", London, George Allen and Unwin, 1972, pp 39-65.

7-Ibid p.44, see also, Moore, F.D., "Therapeutic Innovation: Ethical Bounderies in the Initial clinical Trials of New Drugs and Surgical Procedures", in Freund P.A.(ed), op.cit, he says; "every [surgical] operation of any type contains certain aspects of experimental work." at p 358.

8-Levine, R.J., "Commentaries" in: Gallants, D.M. and Force, P. (eds) Legal and Ethical Issues in Human Research and Treatment, S.P Halsted Press, 1978, p 90, see also, Levine R.J., in Bogomolny, L.R. (ed) Human Experimentation, Dallas, SMU Press, 1976, pp 3-20.

9-See, Walters, L., "General Issues in Experimentation", in Beauchamp, T.L. & Walters LeRoy (eds), Contemporary Issues in Bioethics, California, Dickenson Publishing Company. Inc., 1978,

p 399.

10-Id.

11-Annas G.J., Grantz L.H. and Katz B.F., Informed Consent to Human Experimentation:The Subject's Dilemma, Cambridge, Balliger Publishing Company, 1977, p 11.

12-See for example, Varga A.C., The Main Issues in Bioethics, (rev.ed) N.Y Ramsey, Paulist Press, 1984, p 155, Fried, C., Medical Experimentation: Personal Integrity and Social Policy, N.Y, American Alsevier Publishing Comp. Inc., 1974, pp 25-36, Katz, J., Experimentation with Human Beings, Sage Foundation, 1972, Annas G.J., et al, op.cit, pp 10-21.

13-World Medical Association, Declaration of Helsinki: Recommandations guiding medical Doctors in Biomedical Research Involving Human Subjects. Adopted by the 18th World Medical Assembly, Helsinki, Finland 1964 and as revised by the 29th World Medical Assembly, Tokyo, Japan 1975. The Declaration is of four parts: Introduction. I.Basic Principles. II. Medical research combined with professional care: clinical research. III. Non-therapeutic Biomedical Research involving human subjects: non-clinical biomedical research.

14-Declaration of Helsinki, revised ed; Introduction para.6.

15-Belsey, A., "Patients, Doctors and Experimentation: Doubts about the Declaration of Helsinki", 4 Jour.Med.Ethics (1978), pp 82-85.

16-Levine, R.J., "Commentaries", supra.cit, p 90.

17-Belsey, loc.cit, at p 183.

18-Ibid at p 183-84.

19-Belsey, loc.cit, at p. 184.

20-Id.

21-Levine, R.J., "Clarifying the Concepts of Research Ethics". The Hastings Center Report, (June 1979), pp 21-26, see also Levine, Commentaries, supra.cit, pp 90-92.

22-See Fried, C., "Informed Consent and Medical experimentation", in Beauchamp, T. and Walters, L. (eds), op.cit, pp 437-440, Katz, op.cit, pp 376-79, Chalmers, T.C., "Controlled Studies in Clinical Cancer Research" 287 N.E.J.M [1972], p 75.

23-Levine R.J., "Commentaries" supra.cit, pp 90-92. For example the U.S's National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (N.C.P.H.S.B.B.R) abandoned the distinction between therapeutic and non-therapeutic research and replaced it with the terms: Accepted routine practice and non-validated practice of medicine. For discussion see, Verga, A.C., op.cit, at p 155-56.

24-Verga, op.cit, at p 156.

25-Id.

26-See, in addition to authorities cited in note 22 supra, Mason, J.K, and McCall Smith, R.A., Law and Medical Ethics London, Butterworths, (2nd ed) 1987, pp 257-67, Brazier, M., Medicine, Patients and the Law, Penguin Books, 1987, at p 291.

27-See for example, Faulder, C., Whose Body is it ?, London, Vigaro, 1985, Chapters 5 and 7, Kennedy, I., Treat Me Right, Clarendon Press Oxford, 1988, Chapt 10, in particular, pp 217-20.

28-Brazier, op.cit, at p 291. She mentioned an example in which public concern has been voiced for a large group of patients. A controlled trial involved 3,000 women at risk of conceiving a spina bifida baby. According to a former study similar women appeared to be at a lesser risk of conceiving a spina bifida baby

if treated with special vitamin supplements. To eliminate any doubt about the efficacy of this procedure , a controlled trial was carried out in which the women have been divided at random into 4 groups: one group received the full treatment under trial, other group only of the supplements, a third the other element of the supplement, and the fourth was given a placebo.

29-Helmchem, H., and Müller-Oerlinghausen, B., "The Inherent Paradox of Clinical Trials in Psychiatry" 1 Jou. Med. Ethics 1975, p 169.

30-Id, see also Mason and Mc Call Smith, op.cit, p 258.

31-For example, in a major R.C.T of the efficacy of simple as compared to radical masectomy for cancer of the breast, Sir John Bruce writes:

> "One of the important ethical necessities before a random clinical is undertaken is a near certainty that none of the treatment options is likely to be so much inferior that harm could accrue to those allocated to it. In the present instance .... [it] looked as if the mode of primary treatment made no significant difference , at least in terms of survival". at p 1444.
> Bruce, John, "Operable Cancer of the Breast- A controlled Clinical Trial", 28 Cancer 1443 (1971).

32-See, Helmchem, H and Müller-Oerlinghausen, op.cit, at p 168.

33-Id.

34-See Rudowski, W., "World Health Organization Biomedical Research Guidelines and the Conduct of Clinical Trials", 6 Jour.Med. Ethics (1980) p 58.

35-Mason and Mc Call Smith, op.cit, at p 258.

36-For example, suicidal patients are excluded from R.C.Ts in Psychiatry, see Helmchem and Müller-Oerlinghausen, op.cit, p 169.

37-See, Taylor, K.M., et al "Physicians reason for not entering eligible patients in a R.C.T of Surgery for Breast Cancer" 310

N.E.J.M (1984) p 1343.

38-See, Angell, M., "Patients Preferences in Randomized Clinical Trials" 310 N.E.J.M (1984) pp 1385-87, see also; Marquis, D., "Leaving Therapy to Chance", 13(4) Hastings Center Reports (1983) pp 40-7., Shafer, A., "The Ethics of Randomized Clinical Trial" 307 N.E.J.M (1982) pp 719-24.

39-Mason and Mc Call Smith, op.cit, p 259.

40-Zelen, M.A., "Strategy and Alternative Randomized Designs in Cancer Clinical Trials" 66 Cancer.Treat.Rep.(1982) pp 95-100., Zelen, M.A., "A New Design for Randomized Clinical Trials" 300 N.E.J.M (1979), pp 1242.

41-Ellenberg, S.S., "Randomization Design In Comparative Clinical Trials" 310 N.E.J.M (1984), p 1404.

42-Ibid, pp 1406-07.

43-See Mason and Mc Call Smith, op.cit, p 259.

44-See Angell, M., "Patients' Preferences in Randomized Clinical Trials" 310 N.E.J.M (1984), pp 1385-87.

45-See Dyck and Richardson, op.cit, p 243.

46-Beyer, K., "Limitations of Animal Data for Predicting Safety for Man" in: Use of Human Subjects in Safety Evaluation of Food-chemicals. Proceedings of a Conference. National Academy of Sciences and National Research Council. Pub., 1491 (Wash. D.C 1967) p 43.

47-Marston, R.Q., "Medical Science, The Clinical Trial and Society" in Beauchamp, T. and Walters, L. (eds), op.cit, p 409.

48-Ibid pp409-10.

49-Beecher, H.K., Research and the Individual Human Studies, Boston Little Brown and Company, 1970, at p xiii.

50-Dyck and Richardson, op.cit, at p 224.

51-See Walters, L "General Issues in Experimentation" in Beauchamp, T and Walters, L. (eds), op.cit, at p 400.

52-McCance, R.A., "The Practice of Experimental Medicine" 44 Proc. Roy.Soc.Med.(1951) pp 189-94.

53-Jonas, H., "Philosophical Reflections on Experimenting with Human Subjects" in Freund, P.A., (ed), Experimentation with Human Subjects, London, George Allen and Unwin, 1972, pp 1-31.

54-Ibid at p 14.

55-Ibid at p 13.

56-Ibid at p 28.

57-Ibid at p 12.

58-Schafer, A., "Experimentation with Human Subjects: a critique of the views of Hans Jonas", 9 Jour.Med.Ethics (1983) pp 76-79.

59-Ibid at p 76.

60-Cited by Marston, Q.R., loc.cit, at p 409.

61-Id.

62-Klass, A., There's God in Them Thar Pills, Harmondsworth, Penguin Books, 1975, p 31.

63-Supra cit.

64-McLean, S.A.M., and Maher, G., Medicine, Moral and the Law, Aldershot, Gower, 1983, p 104.

65-Ibid at p 105.

66-For example, companies may keep searching for an alternative drug to one marketed by another company which has been proved to be highly profitable. For further discussion, see McLean and Maher, op.cit, p 105.

67-Id.

68-Declaration of Helsinki rev.ed 1975, Introduction (para.3).

69-Declaration of Helsinki rev.ed 1975, (I.1)

70-Principle one of the Nuremberg Code. Trials of War Criminals before the Nuremberg Military Tribunal, Under Control Council Law no.10, vol II, Nuremberg, oct 1946. April 1949.

71-Dyck and Richardson, op.cit, at pp 244-45.

72-Ibid p 245.

73-Id.

74-See chapter 2 supra.

75-McLean and Maher, op cit, p 116.

76-Ibid p 117.

77-Halushka v. University of Sackatchwan, 53 D.L.R 2nd 1966 p 436.

78-Ibid at p 444.

79-See pp 157-61, supra.

80-Zelen, M., "A New Design For Randomized Clinical Trials" 300 N.E.J.M (1979), pp 1242-45.

81-See Giertz, G., "Ethics and Randomized Clinical Trials" 6 Jour. Med. Ethics (1980) p 55.

82-This is particularly true in therapies for breast cancer, see Taub, S., "Cancer and the Law of Informed Consent" 10 Law Med. Health Care (1982), p 61.

83-Cancer Research Campaign Working Party In Breast Conservation, "Informed Consent: Ethical, Legal and Medical Implications for Doctors and Patients Who Participate In Randomized Clinical Trials" 286 British Medical Jour.(1983) p 1117.

84-Ibid p 1121.

85-Id.

86-The code must be formulated by committees constituted of informed lay members as well as doctors, see Cancer Research Campaign Working Party In Breast Conservation, loc.cit, p 1121.

87-Id.

88-Leading Article: "Secret Randomized Clinical Trials" 2 Lancet (1982), p 78.

89-See for example, Mason and Mc Call Smith, op.cit, p 265.

90-Ayd, F., "Drug Studies in Prisoner Volunteers" in: Beauchamp, T. & Walters, L. (eds), op.cit, p 492.

91-Walters, L., "Experimentation With Specific Subjects Groups" in: Beauchamp, T. and Walters, L. (eds), op.cit, pp 451-52.

92-Trials of War Criminals before the Nuremberg Military Tribunal, Under Control Council Law no.10, vol II, Nuremberg, oct 1946. April 1949.

93-McLean, S. and Maher, G., op.cit, p 118.

94-Id.

95-See Annas, Glantz and Katz, op.cit, p 6.

96-In effect in this case chronically ill patients were injected under the skin with life cancer to determine how long it would take them to reject such sells. See generally, Katz, J., op.cit, Chapt.1.

97-McLean, and Maher, op.cit, at p 112.

98-See Katz, J., op.cit, Chapter one, see also Veatch, R.M., and Sallito, S., "Human Experimentation:The ethical questions Persist" The Hastings Center Report (June 1973).

99-United Nations Educational Scientific and Cultural Organization (U.N.E.S.C.O). Division of Science and Technology Policies. Fact-Sheet on Research Ethics in Europe, 1988-1989 at the international and the intergovernmental level. U.N.E.S.C.O/N.S/ROU/699.

100-Paras (4), Resolution A.2-78/88 adopted on Sept.88 on European Harmonization of Medicoethical Questions, based on the report drawn up on behalf of the European parliament's committee on Legal Affairs and Citizens' rights, rapporteur Mr. Ulburghs, J., bearing

the above reference and dated 17/03/1988 (Eng. 19 pp).

101-Ibid, para.11.

102-Ibid, para.12.

103-Ibid, para.13.

104-Resolution A 2-327/88 On the Ethical and Legal Problems of Genetic Engineering, based on the report drawn up on behalf of the European Parliament's committee on Legal Affairs and Citizens' rights, rapporteur Mr. Rothley, W., bearing the above reference and dated 19/12/1988.(Eng.49 pp)

105-Resolution A-372/88 On Artificial Insemination 'In Vivo' and In Vitro', based on the report drawn up on behalf of the European Parliament's committee on Legal Affairs and Citizens' rights, rapporteur Mr. Casini, C., bearing the above reference and dated 30/01/1989. (Eng. 27 pp.)

106-McLean and Maher, op.cit, at p 112.

107-Id.

108-Barber, B., "The Ethics of Experimentation with Human Subjects" in: Beauchamp, T. and Walters, L. (eds), op.cit, p 442.

109-Applbaum, P., Lidz, C. Meisel, A., "Informed Consent", Oxford University Press, 1987, pp 221-22.

110-Jaffe, L., Law as a System of Control, in: Freund, P.A. (ed): Experimentation with Human Subjects, George Allen and Unwin, 1972, pp 198-99.

111-Previously known as the Committee on Safety of Drugs.

112-See, for example, the Report of the Royal College of Physicians, Research on Healthy Volunteers, vol 20 No 4 Journal of the Royal College of Physicians of London. (Oct. 1986).

113-See, for example, the Report of the Royal College of Physicians, The Relationship Between Physicians and the Pharmaceutical Industry,

vol 20 No 4 Journal of the Royal College of Physicians of London. (Oct. 1986).

114-Ibid p 6-8.

115-"Responsibility in Investigations on Human Subjects" vi British Medical Journal (1963), at pp 177-8. see also Brititish Medical Association, in 282. B.M.J (21 Marsh 1981).

116-see, for discussion, Brazier, op.cit, p 113.

117-Thompson, I.E., et al. "Research Ethical Committees in Scotland" 282^{1} Brit.Med.Jour. (1981), p 719.

118-Id.

119-For trenchant criticism of ethical committees and professional attitudes, see, Faulder, C., Whose Body is it?, London, Virago, 1985, pp 95-100.

120-Brazier, op.cit, p 285.

121-McLean and Maher, op.cit, P 118.

122-Giertz, G., op.cit, at p 56.

123-McLean and Maher, op.cit, p 119.

124-Mason and McCall Smith, op.cit, p 268.

125-Supra.cit

CHAPTER SIX

THE CONSENT DOCTRINE IN HUMAN EXPERIMENTATION

Following the general discussion of the ethics of human experimentation outlined in chapter five, attention will turn now to an exploration of the development of the consent doctrine in the experimental setting.

It has been noted that despite some apparent similarities in the issues raised, the requirement of obtaining the prospective subject's consent to human experimentation has developed quite separately from that to therapy.[1] Consent to treatment has been created by case law, with the courts playing an important role.[2] Consent to human experimentation, however, has been shaped by professional codes, statutes, and administrative guidelines in addition to judicial regulations.

It is noteworthy at the outset of this discussion that the use of human subjects in research is as old as medicine itself. What is new, however, is the concern about its consequences and about the protection of the human subjects. The earliest moral and legal concern has historically been to control the risks presented to the subjects by experimentation. The main objective has been to ensure adequate levels of safety and, therefore, to prevent abuses of subjects. The requirement of consent first appeared in research codes and guidelines without specific reference to justificatory principles. Along with the development of research ethics, however, it has become firmly established that there are two primary goals for policies covering the use of human subjects in research; controlling imposed

risks, i.e., a beneficence-based consideration, and providing for informed and valid consent which is an autonomy-based consideration.

The modern concern with informed consent in human research grew gradually only after the occurrence of the unprecedented cruelties and generally inferior science administered by the Nazi physicians in the course of the Second World War. Prior to this period little attention was paid to the circumstances under with research should be carried out, including the issue of consent. This does not suggest by any means, however, that issues in the ethics of research never arose in earlier periods. Public concern in Germany, for example, culminated in 1931 in the promulgation of guidelines that required clear explanations of innovative or experimental treatments.[3] Another example prior to World War II is found in public concerns about the consent practices involved in Walter Reed's experiments on yellow fever.[4] On the other hand a review of the appellate cases decided in the U.S.A and in the U.K in the human experimentation field prior to this period, reveals the relatively radical shift in the law's attitude toward human experimentation. Therefore, before considering the Nuremberg trials, a review of some of these appellate decisions is in order. This will be followed by a discussion of the provisions of the Nuremberg code and the Declaration of Helsinki, particularly those dealing with the requirement of consent. The post-war appellate decisions are also relevant to the present discussion. Courts in these cases, as will be seen later, did not question the appropriateness of the experimental interventions. Rather, they focussed on the requirement of securing a valid and informed consent from the prospective subject. The last section of the present discussion will be concerned with the current status of the consent doctrine in the experimental setting.

6 : 1 PRE-NUREMBERG APPELLATE DECISIONS:

It is submitted that before the promulgation of the Nuremberg code, any existing legal principles in the experimental setting emerged through the appellate court decisions governing actions for malpractice, and through a few isolated cases involving injury from experimental techniques. These early decisions did not distinguish clearly between innovative medical practice and medical research. The courts viewed both innovation and experimentation as unjustified departures from standard medical practice, although this attitude was directed more at protection of the patient than at the restriction of experimentation.

The first case of historical significance to reach an appellate court was the 1767 English case of Slater v. Baker.[5] The case involved a novel technique - the use of 'heavy steel thing that has teeth' to 'stretch and lengthen the leg'- for healing leg fractures, that was used without the consent of the patient and that deviated sharply from standard practice. In confirming judgment against the defendants the appellate court made the point that

> "Since it appeared from the evidence that this was the first time this device had ever been used, it was a rash action, and he who has acted rashly acts ignorantly, and is accordingly responsible for the consequences of his actions"[6]

Slater has been cited as an experimental case, a malpractice case and a consent case.[7]As some commentators noted, the mere fact that the physician proceeds with a technique for the first time does not subject him or her anymore to absolute liability for its consequences.[8]

Another significant decision came from the court of New York in 1871 in the case of Carpenter v. Blake.[9] This case involved treatment of a dislocated arm. Following the administration of the treatment, the physician failed to inform the patient that his arm should either remain in a sling or be held on a pillow at a right angle for a period of time, information that was found to be standard medical practice at the time.

The court held that if an approved procedure already exists, it can only departed from at the physician's peril, leaving physicians with virtually no freedom to experiment. A similar approach was followed in the case of Jackson v. Burnham.[10] It was held;

> "[I]f a physician sees fit to experiment with some other mode, he should do so at his peril. In other words, he must be able, in the case of deleterious results, to satisfy the jury that he has reason for the faith that was in him, and justify his experiment by some reasonable theory."[11]

Few other additional cases dealt with these issues prior to the period in question. Most of these cases treated any departures from standard medical practice as 'experimentation' and considered it as an improper procedure.[12]

However, in 1934 the court in Brown v. Hughes [13]followed a different approach when it reluctantly acknowledged that some experimentation was necessary for the advance of science, although still equating experimentation with rash treatments. The court in *Brown* appeared to express a slight openness toward deviation from routine and accepted practice referring to the use of "rash or experimental method" as putting the physician at risk of liability, but later acknowledging that only "total abandon" should give rise to

liability, or else physicians would not use their learned judgment in the advance of science.[14] Therefore, although experimentation was still viewed as extreme, at least the court acknowledged the need for some experimentation in order to achieve medical progress.

In the following year, Fortner v. Kock[15], added a new dimension to judicial understanding of the role of human subjects in medical research. The court reiterated the view that experiments involving human subjects are needed in order to achieve medical progress. The case involved a sixty year-old patient who was suffering from a swollen knee. The physician diagnosed and treated the patient for bone cancer. The treatment, however, proved inappropriate as the patient's condition got progressively worse until the leg broke open and raised a "cauliflower mass", causing sharp pain. The patient consulted another physician, and following the performance of different diagnostic tests, the patient was diagnosed and treated successfully for syphilis.

The appellate court commented on the failure of the first physician to carry out standard diagnostic tests. The court held in particular;

> "We recognise the fact that, if the general practice of medicine and surgery is to progress, there must be a certain amount of experimentation carried on, but such experiments must be done with the knowledge and consent of the patient or those responsible for him, and must not vary too radically from the accepted method of the procedure."[16]

The court in *Fortner* removed human experimentation from the category of forbidden activities as long as it was not "too radical" and was done with the patient's acquiescence.

It should be noted, however, that the court was primarily

concerned with permitting medical departures that are potentially in the interests of the patient. Therapeutic beneficence therefore, provided the primary justification for permitting the research. Most of these early cases dealt with so-called therapeutic research, i.e., the physician was attempting to cure the particular patient, and was sued for injuries arising from that attempt. It is interesting to note in this respect that some scholars[17] have attributed the judicial conservatism that characterized human research at that time in part to such situations, and particularly when conventional treatments are available.

The main point to note from the decision in *Fortner*[18]is its acknowledgement of the importance of two fundamental elements in the justification of experimentation involving human subjects; an acceptable risk-benefit balance and the provision of valid consent.[19]

In 1941, another American case came even closer to contemporary judicial thinking. That was in Slammer v. Bd.of Regents.[20] In this case the physician had his licence to practice medicine suspended after he was found guilty of fraud and deceit by the state's licensing authority for using an experimental procedure in cancer treatment. On appeal there was evidence that the physician had informed the patient of the experimental nature of the procedure and of the possibility of benefitting from it without being exposed to any risk of harm. Interestingly, the procedure proved to be very effective, and a complete cure followed the administration of the experimental treatment. In finding for the physician, the court held;

> "Initiative and originality should not be ... effecti-vely stifled, especially when undertaken with the patient's full knowledge and consent, and as a last resort.[21]

It is submitted that despite their language these early cases dealt, in fact, with innovation and not with the conduct of systematic human experimentation. Thus these early developments can be of great assistance, as Faden and Beauchamp pointed out, in "shed[ing] light on the evolution of values in research with human subjects"[22] but these have no direct causal influence on later developments in 'informed consent'. As mentioned earlier, the modern concern with consent as a legal and ethical requirement in the experimental setting developed gradually after the trial of Nazi physicians for the atrocities they had committed in the name of medical science during World War II. In effect, the trial helped focus the attention of the world on the ethics of medical research, and set the boundaries that should be observed when involving a human subject in scientific research. These bounderies became internationally known as the Nuremberg Code, and were later developed in the Declaration of Helsinki.

6 : 2 INTERNATIONAL CODES OF ETHICS:

A-The Nuremberg Code:

The code was articulated as part of the judgment in the case of United States v. Karl Bandt et al[23], which involved the trial of twenty three German physicians for "war crimes" and "crimes against humanity" in the course of the Second World War.

Testimony at the trial revealed that concentration camp inmates and prisoners of war had been subjected to so-called experiments, many of which were carried out without a valid scientific purpose, and without either the knowledge or the consent of the subjects. The procedures performed ranged from the deliberate inoculation of inmates with typhus bacilli, to their exposure to cold water and low air

pressure to observe the events that would lead to their death.[24] The defendants claimed that their experiments with both prisoners of war and civilians were consistent with the ethics of the medical profession, and that they were as valid as previously published experiments on venereal diseases, plague and malaria. The court found, however, that with the exception of an insignificant number of medical experiments on human subjects, most of the Nazi experiments were far from being in comformity with the ethics of medical science. The court held that only "certain types of medical experiments on human beings, when kept within reasonably well defined bounds, conform to the ethics of the medical profession generally."[25] The court then described these 'bounds' in the form of ten "basic principles [that] must be observed in order to satisfy moral, ethical and legal concepts" in the conduct of human experimentation. These principles constituted the Nuremberg Code.

Principle one of the code states, without qualification, that the primary consideration in research is the subject's voluntary consent which is "absolutely essential". In order to be valid, the subject's consent must be; voluntary, competent, informed and comprehending.[26] The rest of the principles dealt with the general bounds within which experiments should be carried out and delineated the conditions under which a human subject has the ability to volunteer. As has been noted, although the code did not explicitly so state, the requirement of securing the prospective subject's valid consent becomes relevant only after an appropriate risk/benefit assessment has been made.[27] Presumably, the benefits must at least offset the potential risks to the subject. For if the risks outweigh the rewards, the experiment may be unethical and therefore invalid from the beginning. Furthermore, the code did not describe how to secure the subject's consent and how

the limits of the risks are to be defined. The court reasoned that such determinations were beyond its sphere of competence.

In this respect some researchers expressed their dissatisfaction with some provisions of the code. Beecher[28], for example, pointed out that the absolute requirement of informed consent may preclude experimentation with certain types of subjects namely, the mentally ill. He also pointed to the requirement of an understanding or enlightened decision as being difficult to satisfy, for he believed that many subjects were incapable of comprehending the details of the techniques of clinical research.

In any event, regardless of these so-called fallacies or errors, the Nuremberg code proved influential in the years that followed its promulgation. In particular, the code stimulated worldwide discussion about the ethics of conducting experiments with human subjects and led to the promulgation of subsequent codes of ethics in many countries.[29] Most of these national codes used the Nuremberg code as a model and many of them reflected it in many aspects. Some codes, however, deviated significantly, toward greater leniency with respect to consent. The statement of the British Medical Research Council (B.M.R.C), for example, made the distinction that later appeared in the Declaration of Helsinki[30], between therapeutic experiments (experiments that were likely to benefit the patient subject), and non-therapeutic experiment (experiments that were not designed to benefit the subject). The B.M.R.C made consent required only in the non-therapeutic experiments.[31]

It should be noted, however, that soon after its acceptance, the Nuremberg code came to be viewed as inadequate to govern the complex variety of situations arising in the expanding fields of human research. On the other hand, as national codes developed, the need for

an international restatement of common principles arose. In response, in 1964, the World Medical Association adopted the Declaration of Helsinki.[32]

B-The Declaration of Helsinki:

The Declaration also emphasized the legal and ethical requirement of valid and informed consent. It made consent a central requirement of ethical research. This requirement was linked to an influential distinction that was proposed by the Declaration between therapeutic and non-therapeutic research. The former is defined in the Declaration as "medical research combined with professional care"[33], and is permitted as a means of acquiring new medical knowledge "only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient."[34] The latter is defined as "purely scientific and without direct diagnostic or therapeutic value to the person subjected to the research."[35]

The prospective subject's valid consent is required in all instances of non-therapeutic research unless the subject is incompetent, in which case his or her consent must be obtained by proxy.[36] However, in therapeutic research the subject's consent is not required "[i]f the doctor considers it essential" not to secure it, but "the specific reasons for [not obtaining the subject's consent] should be stated in the experimental protocol for transmission to the independent [review] committee."[37]

That is, according to the Declaration, informed consent is not required if it is not "consistent with patient psychology"[38] The justification of this broad exceptive provision rests on the same beneficence-based premises that support the physician's therapeutic privilege in therapy. Some commentators[39] pointed to this exceptive

provision as being a serious flaw, especially if the physician's judgment in not securing the subject's consent is checked by inattentive review committees.

C-The Legal Standing of International Codes:

Although the Nuremberg proceedings were based on international agreement, namely Control Council Law 10, they were conducted by American Military Tribunals composed of American judges and proceeded with according to American Procedural rules.[40] This fact led many to deny the international character of the Nuremberg Trials.[41]

It should be noted in this respect that the British Government also refused to take responsibility for the subsequent Nuremberg Trials[42] On the other hand the U.S Supreme Court declined to hear any appeals from the Tribunal stating that it did not have the power to review the proceedings of an international court.[43] In addition, its adoption by the United Nations General Assembly on Dec 11, 1946, and its use as a basis for other international documents such as the Declaration of Helsinki [44] have been said to have confirmed the view that the Nuremberg Code is part of the international common law.[45] Nevertheless, the code was not enforceable under the law of individual nations. In the U.S.A, for example, the code has only been used as authority by one court. That was in Kaimowitz v. Mich. Dept. Mental Health [46] which involved a psychosurgical procedure. The court considered the Nuremberg Code as a proper standard against which to judge the sufficiency of the consent obtained for the proposed experimental brain surgery.

With respect to the Declaration of Helsinki, although there is no doubt about its international character, like the Nuremberg code it is not legally enforceable. These codes, however, remain valuable because

of their symbolic function which consists in reminding investigators of the nature of the human subject and the respect which is due to his or her personal integrity in any kind of research.

6 : 3 POST-NUREMBERG APPELLATE DECISIONS:

After the promulgation of the Nuremberg Code, experimentation became firmly established as a responsible and legitimate scientific technique, and courts focused on the necessity of securing the subject's valid and informed consent rather than on the novelty of the procedure.

With the exception of a series of cases involving tissue transplants from minor donors[47], appellate court decisions on systematic human experimentation were relatively rare. Most of the cases that went to courts involved innovative treatment and were decided in the U.S.A. The 1965 Canadian case of Halushka v. University Board of Saskatchewan[48], is, however, the only post-Nuremberg case involving non-therapeutic research on a normal volunteer. Plaintiffs in these cases alleged that their consents to experimental procedures were not informed. These cases are outlined under the headings of therapeutic and non-therapeutic research.

A-Therapeutic Research:

The first case that viewed human experimentation as not only legitimate, but also as an enterprise that should be encouraged, at least when conventional or standard treatment proved ineffective, was Baldor v. Rogers,[49] a case that involved treatment for cancer. Suffering from lip cancer, the patient informed his physician that he did not want surgery, (a treatment that was accepted as standard

medical practice but not certain in the cure of the condition in question). Accordingly, the patient was submitted to a treatment which consisted in drug injections for a period of nine months at the end of which the treatment proved ineffective as the patient's condition was getting worse. The patient was discharged and sent home. He based his action for malpractice on the allegation of both wrongful experimentation and abandonment.

During the trial the court commented on the role of the medical profession in attempting to develop a cure for cancer. It was held, in particular, that no malpractice can be found for the mere fact that the physician experimented with possible cures, "if there is no certain cure and if the physician did not indulge in quackery by representing he has."[50] On rehearing the court, however, held the investigator responsible for the disclosure of other options to the patient subject from the moment it became evident that the experimental treatment was not effective;

> "All of the medical testimony emphasizes the fact that time is of the essence in treating cancer. It is the doctor, and not the patient, who holds himself out to be, and must be, best equipped to detect the warning signs. And when the treatment is ineffective, it is the doctor who must know it first and recommend other action."[51]

In the Scottish case of Mc Hardy v. Dundee General Hospitals Board of Management,[52]the court went even further than merely acknowledging the necessity of finding cures for existing diseases. In finding for the defenders in an action for negligence in diagnosis and treatment, the court held that given the nature of the medical art and the difference of opinion among professionals of the highest qualification and the widest experience both in diagnosis

and treatment, the doctor is not to be held liable for negligence for a mere error of judgment or even an error in diagnosis. "[T]his should be so", the court went on, because of the fact that

> "currents of medical opinion and practice, particularly in matters of treatment of disease, are subject to fluctuation and change according to changes in available knowledge and of professional practice in its application."[53]

and thus,

> "...the search for further knowledge and experience should not be inhibited by indue apprehension of charges of negligence for the consequences to a patient of treatment or diagnosis where such may diverge fron the normal.[54]

The next case on the issue involved a novel approach to disease, in this case scoliosis (curvature of the spine). That was in Fiorntino v. Wenger[55], which also emphasized the quality of the patient subject's consent.

Five years before using it on the plaintiff's fourteen year-old son, the physician developed a technique (surgery) in the treatment of the condition in question. Five times it had produced "unexpected results." The procedure involved the insertion of a steel bar or "spinal jack" screwed into the vertebral column. Following the performance of the procedure on the plaintiff's son, the latter suffered an "exsanguinating hemorrhage" which caused him to die.

The court in this case did not discuss the appropriateness of the experiment. Rather it focussed on the necessity to disclose the known risks of the procedure. The court held that, because the procedure was "novel and unorthodox", it was the physician's duty to inform the

parents of the "risks incident to or possible in its use."[56] Moreover, the court also held the hospital liable for failure "to ascertain that the physician had made such a disclosure before permitting the operation to take place."[57]

In another case two Texas courts illustrated the point that consent is now seen by many courts as much more important than the intrinsically experimental nature of the medical intervention. That was in Karp v. Cooley[58], where the two courts found the first and only implantation of an artificial heart into a human being to be exclusively therapeutic. As mentioned before, the patient in this case agreed to an implantation of an artificial heart which kept him alive for approximatively sixty-four hours, but he died a short period after it was replaced by a human donor heart.

In an action for malpractice, the patient's wife alleged that the physician failed to obtain valid and informed consent prior to the performance of the experimental surgery. The court found, however, that the physician had discussed the procedure with the patient on more than two occasions, and that the latter had signed two consent forms; the hospital's general consent form that should be signed upon admission, and a much more specific one about three weeks after hospitalisation and just before the performance of the surgery.[59]

The plaintiff alleged that she did not understand how experimental the procedure was, and that her husband did not read the document. Both arguments were rejected. The court held that under the law only the patient had to consent to the procedure and that in the case before the court the patient was charged with reading the consent document by the fact of his signature, even though he, in fact, did not. The plaintiff's last and important argument was that the physician did not inform her husband of the nature of the artificial

heart so that to enable him to make an informed decision as to whether to agree to the surgery being performed. In dismissing this argument the court stated;

> "the record contains no evidence that Mr. Karp's treatment was other than therapeutic and we agree that in this context an action for experimentation must be measured by traditional malpractice evidentiary standards."[60]

That is, although this experimental surgery was the first of its kind to be performed on a human being, the court viewed it as a therapeutic one. This proposition has been rejected by many commentators;

> "while the case points up the great utility of a consent form that at least attempts some specifity,[to hold that the surgery] was not primarily an experiment, albeit a therapeutic one, is untenable"[61]

Furthermore, it was remarked that the court's decision was drawn from either the fact that the judge was not convinced by the evidence presented on this issue, or that he considered the magnitude of the risks involved in the surgery irrelevant.[62] Had the court viewed the procedure in this case as an experimental one, it could have applied Federal Health, Education and Welfare guidelines relating to consent forms, which required at that time a complete disclosure of the possible risks and benefits of the experimental intervention.[63] It is worth noting in this respect that in 1974 the American National Heart and Lung Institute (N.H.L.I)[64] published supplemental criteria for the human testing of therapeutic devices under its research contracts.[65] This suggests that any investigator currently engaging in human research whose funding derives from H.E.W is required to

follow these and other N.H.L.I guidelines.

Similar guidelines were published by the Committee on Ethics of the American Heart Association in early 1976[66], regarding the clinical use of the left ventricular assist device (L.V.A.D), a device which is a partially implanted artificial heart for temporary use following some forms of heart surgery. The aim of these guidelines was to alleviate the difficulties that thoracic surgeons were facing when securing informed and valid consent, in particular, from terminally ill or dying patients to such experimental interventions. In order to ensure that meaningful consent be obtained[67],the committee recommended that a third party take part in the consent procedure. It was said;

> "The participation of a third party, which may be more than one person, to mediate the consent process without being caught up in the force of its dependencies ought to make the consent decision more genuine. It should also be a source of reassurance and comfort to both family and paramedical personnel, as well as to the patient and his doctor."[68]

B: Non-Therapeutic Experimentation:

It is submitted that there are no post-Nuremberg appellate court decisions involving non-therapeutic experimentation on a normal volunteer neither in the U.S.A nor in Britain. The leading authority on this issue is, however, the Canadian case of Halushka v. University of Saskatchewan.[69] While United States courts would probably follow Canada's lead and require full disclosure of potential risks to all participants in this type of experiments, British courts should, as has been suggested by some commentators[70], adopt the same approach.

The Halushka Case:

The case involved the testing of a new anaesthetic drug. In effect, the subject in this case volunteered to submit to the test in question after being informed by one of the responsible investigators that it was a "safe test and there was nothing to worry about", and that he would receive $50 as remuneration for each test. The subject was not informed that the test involved a new drug, of which the researcher had no previous knowledge nor that, being an anaesthetic, there was risk involved in its use. Moreover, he was denied any explanation regarding the way in which the test would be proceeded with or the method that would be followed. He signed a consent document which reads, in part;

> "...I have volunteered to submit for tests upon my person for the purpose of study of Heart and Blood Circulation Response under General Anaesthesia.
> The tests to be undertaken in connection with this study have been explained to me and I understand fully what is proposed to be done. I agree of my own free will to submit to these tests, and in consideration of the remuneration hereafter set forth, I do release the chief investigators. Dr. G.M Wyant and J.E Merriman....are absolved from all responsibility and claims for whatsoever, for any untoward effects or accidents due to or arising out of said tests, either directly or indirectly"[71](emphasis added).

It is interesting to note that before signing the document, the subject asked and was told that 'accidents' in the consent form referred to those that might occur in his home, not in the hospital.

During the performance of the test, the subject suffered heart stoppage and remained unconscious for four days and hospitalized for another ten days. On his discharge, at which time he was given his $50, the subject asked if that was all he would get for what he had been through. He was told that he could earn more if his mother or

elder sister would submit to a similar test.

In an action for damages, the subject alleged trespass and negligence in the conduct of the test. A jury awarded $22,500. The experimenters appealed on the ground that the subject consented to the test, and that the trial judge misdirected the jury in respect of the consent obtained and further erred in instructing them that this was a case of a doctor and patient relationship, whereas he should have charged the jury that it was a contractual relationship. The appellate court held, however, that the duty "imposed upon those engaged in medical research...[was] as great as, if not greater than, the duty owed by the ordinary physician or surgeon to his patient"[72], and continued;

> There can be no exceptions to the ordinary requirements of disclosure in the case of research as there may well be in ordinary medical practice. The researcher does not have to balance the probable effect of lack of treatment against the risks involved in the treatment itself. The example of the risks being properly hidden from a patient when it is important that he should not worry can have no application in the field of research. The subject of medical experimentation is entitled to a full and frank disclosure of all the facts, probabilities and opinions which a reasonable man might be expected to consider before giving his consent."[73]

The same approach has been adopted by one New York administrative agency (The state licensing board) in an American case of non-therapeutic experimentation which involved disciplinary proceedings against the principal investigators who subjected their terminally ill patients to some experiments without their real consents. That was in the Jewish Hospital for Chronic Diseases Case.[74]

In a study of immune reaction, twenty two terminally ill patients

were injected under the skin, without valid consents, with live cancer cells to determine how long it would take them to reject such cells. Following the publicity that arose from this study, an action was brought by the Attorney General of New York before the state licensing authority, then the Board of Regents, to revoke the medical licenses of the principal researchers. They were sentenced to have their licenses suspended, but the sentence was never carried out, and the physicians were placed on probation. The Board of Regents Discipline Committee[75], however, published an opinion concerning the necessity of full disclosure in the non-therapeutic setting, including, the fact that the cells being used were cancer cells in the present case. It was said;

> "A physician has no right to withhold from from prospective volunteer any fact which he knows may influence the decision. It is the volunteer's decision to make, and the physician may not take it away from him by the manner in which he asks the question or explains or fails to explain the circumstances"[76].

The committee then made it clear that this case did not concern "the usual doctor/patient relationship", but an investigator/subject rela-tionship, and therefore there was "no basis for the exercise of the usual professional judgment [regarding disclosures that may be potentially harmful to the patient] applicable to patient care."[77] The major point underlined by the committee was, however, that

> "No person can be said to have volunteered for an experiment unless he has first understood what he was volunteering for. Any matter which might influence him in giving or withholding his consent is material. Deliberate nondisclosure of the material fact is no different from deliberate misrepresentation of such a fact....The alleged oral consents that they obtained after deliberately withholding this information [that

> the cells were cancer cells] were not informed consents and were, for this reason, fraudulently obtained"[78]

The main point to note from the last two cases is that a normal volunteer can never be considered as a patient. Thus, the exceptions to full disclosure of all material or significant facts such as the "therapeutic privilege" that might find some application in the doctor/patient relationship, can never apply in a researcher/subject relationship.

6 : 4 CURRENT REGULATION ON CONSENT TO HUMAN RESEARCH:

It should be reiterated at this stage that the United States took the lead in issuing regulations with respect to controlling the conduct of human research. As was mentioned earlier, since 1966 an extensive system of regulation of research with human subjects has been erected.[79] The review process, for example, has been created primarily by federal legislation then supplemented with statutes by individual states.

Most of these regulations and guidelines dealt with the requirement of informed consent. Current federal regulations, for example, define informed consent as;

> "...the knowing consent of an individual or his legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion."[80]

With respect to information disclosure the current regulations specify in detail what must be disclosed. Eight basic elements of

informed consent must be disclosed to prospective subjects;

> (1) a statement that the study constitutes research, an explanation of its purposes and the expected duration of subject involvement, and a description of the procedures involved, with experimental procedures identified as such;
> (2) a description of risks and discomforts that are "reasonably foreseeable";
> (3) a description of possible benefits to subjects and others;
> (4) disclosure of appropriate alternative treatments, if any;
> (5) a statement describing the extent of confidentiality of records generated;
> (6) an explanation of whether compensation or treatment will be available if injuries occur;
> (7) a note as to who can be contacted with questions or reports of injuries; and
> (8) a statement as to the voluntary nature of participation and the subject's right to withdrawal at any time.[81]

Moreover, more detailed supplementary guidelines have been issued by the D.H.H.S and meant to protect subjects forming the so-called vulnerable groups namely, the mentally handicapped adult persons, children and prisoners, i.e., the type of subjects who are believed to be less able to assimilate the experimental nature of the procedure or its potential risks of harm.

In this respect, some commentators[82]pointed out that this kind of regulation allows much more precise specification of controls on consent than does an approach that relies heavily on case law.[83] They noted, however, that existing regulations give no guidance as regards "the specific information that should be conveyed, the emphasis different elements of disclosure should receive, or the method accomplishing meaningful explanation."[84] Concerning the role

of institutional review boards (I.R.Bs) and their performance, in particular, in relation to informed consent, it has been noted that I.R.Bs tend to consider the wording of consent forms rather than the more substantial issues of consent and the conduct of research.[85]

In any event, regardless of what has been noted against it, the system of regulation has, at least, sought to control the human research enterprise and important issues - in particular, informed consent.

In contrast to the U.S.A, the situation in the United Kingdom is less developed with regard to monitoring and controlling the conduct of human research by way of administrative regulation and legislation. As has been said, in Britain "[t]he law's role is limited to intervention when disaster has struck."[86] In effect, apart from legislation relating to experimentation with new drugs[87], there is still a remarkable lack of specific legislation as regards the conduct and control of experimentation, including rules governing consent to participation in trials.

A-The status of consent to experimentation in the U.K:

In the absence of specific legislation governing consent to human research, it is necessary to rely on principles governing the issue in the common law and international ethical codes like the Declaration of Helsinki. It should be reiterated in this respect that, being international, these guidelines are unenforceable but not without value. These guidelines may be of great assistance to all those engaged in human research since they provide the theoretical framework within which research may legitimately be carried out.[88]

With respect to common law, most principles governing consent in therapy may be applicable to the experimental setting. But, because

experimentation may be clinical or non-clinical, the legal response will differ in certain aspects depending on the type of experimentation.

With respect to clinical innovation which is usually defined as deviation from standard medical practice,[89]the law is well settled as regards its lawfulness and legitimacy and the test for establishing liability in such a case. In the leading Scottish case of Hunter v. Hanley[90], it was held;

> "To establish liability by a doctor where deviation from normal practice is alleged, three facts require to be established. First of all it must be proved that there is a usual and normal practice; second it must be proved that a defender has not adopted that practice; and thirdly (and this is of crucial importance) it must be established that the course the doctor adopted is one which no professional man of ordinary skill would have taken if he had been acting with ordinary care."[91]

It has been argued in this respect that the law is more concerned with the reasonabless of the deviation from standard practice than it is with the individual's rights to self-determination or personal integrity which "form the central theme of the ethical codes [on human research]."[92] As McLean[93] has pointed out the law should also be concerned with the provision of information and the obtaining of the subject's consent which are also as significant as the technical aspect of the medical act. She says;

> "If the doctor is to fulfill his or her obligation to respect the patient, and to meet the demands of the ethical code outlined in the Declaration of Helsinki, then information must be given to the patient, and a real consent provided."[94]

For consent to be real information disclosure should include the

innovative nature of the treatment and the doctor's reasons for choosing such a strategy.

The question which one may ask at this stage is whether the current law is ever ready to enforce this fundamental right. Some scholars[95] believe that the *Bolam* test[96] as modified in *Sidaway*[97],

> "would be as likely to be followed in experimentation as in treatment and a failure of disclosure would probably have to be of a serious nature for it to be regarded as negligence."[98]

Since, however, the Declaration of Helsinki[99] mentioned no standard practice, and this is the ethical code that guides both clinical and non-clinical experiments, the assessment of standard practice relating to information disclosure must be made in the light of the rules of the Declaration.[100]

Concerning non-therapeutic experiments, the assumption is that the investigator must give a full disclosure of information to the volunteer since there is nothing which may prevent him or her from doing so, at least, as far as the subject's condition is concerned. There is no room for the principle of therapeutic privilege to apply in this type of experiment since there is no need to assess the harm that may ensue between undergoing or foregoing the procedure. Therefore, information disclosure has to be made to the patient's satisfaction.[101]

B-Compensation for Injury In Experimentation:

At the present time, the only remedy for redressing grievances in experimentation is suing in negligence. In order to succeed in such an action, the subject has to prove either that the investigator was

negligent in informing him or her, or negligent in the performance of the experiment depending on the basis of the claim, i.e., uninformed consent or professional negligence.

Most scholars[102] agree to the fact that the law of negligence does not provide an adequate mechanism for vindicating the subject's right to compensation when he or she suffers injuries in research. For the subject must not only confront the many drawbacks of the negligence format in general but also the specific ones raised in experimentation. Perhaps Brazier[103], has best highlighted the point when she has said, "[i]f proving negligence in the operation of standard procedure is difficult, how much more difficult it is to prove negligence in embarking on novel procedures."[104] For example, in relation to the legal and ethical validity of the research project the investigator will have taken the necessary precautions including obtaining the approval of the research ethical committee. It necessary follows, as Mason and McCall Smith[105] observed, that on the grounds of foreseeability, if an accident or mishap does occur it "will not have been reasonably likely."[106]. The need for a defined method of compensation in such cases has already been noted.[107] In this respect, while retaining the law of negligence for medical accidents generally the Royal Commission on Civil Liability and Compensation for Personal Injury (Pearson Commission)[108] recommended a strict basis of liability in the context of medical research. It was reasoned that the person who put himself at the service of the community is entitled to compensation from the community.[109] A system based on strict liability, it is believed, would alleviate the many difficulties the aggrieved subject usually encounters in seeking damages.

6 : 4 CONCLUSIONS:

The law has gone through a radical shift in its attitude to human research. Before the promulgation of the Nuremberg Code, systematic human research was not directly recognized by the law. As was shown at the begining of this discussion, appellate courts treated any deviation from standard, or routine and accepted practice as malpractice and held the physician responsible for the injuries resulting from the experimental procedure, particularly when conventional treatments were available.

It was not until the trial of the Nazi physicians before the Nuremberg Tribunals and the promulgation of the Nuremberg code that human research became recognized as a legitimate enterprise. And most subsequent codes of ethics whether they be national or international, for example, the Declaration of Helsinki, emphasized the idea that human experimentation is necessary for medical progress, and focussed on the legal and ethical conditions that should be met before subjecting human beings to experimentation. Two primary goals became important for policies covering the use of human subjects in research; controlling imposed risks, i.e., a beneficence-based consideration, and providing for informed and valid consent which is an autonomy-based consideration. Hence courts no longer questioned the novelty of the procedure but rather concentrated on the validity of the subject's consent to research.

With the development of the research enterprise and its expanding fields, different types of experiments appeared, and it has become necessary that experimentation be controlled by specific legislation. One of the many reasons that has made state's legislation necessary is the judicial inability to control adequately the research enterprise.

As has been pointed out courts can only control experimentation in a retroactive way, but they cannot prevent disasters. In addition, an aggrieved subject can only with difficulty succeed in receiving compensation. For in the absence of specific dispositions on this issue the subject has to go through the negligence action, with all of its difficulties.

The issue of consent to research, in particular, is far from being clear in the U.K. The *Sidaway* test, it is said, is likely to be also applied in clinical innovation. It is recommended, however, that if such an approach is to be followed, the assessment of standard practice must be made according to Declaration of Helsinki's guidlines on the issue. It should be noted, however, that given the lack of precision in the current status of consent, one would reiterate the view that a proper definition of all its priciples be outlined. Such objectives can only be achieved by the promulgation of specific legislation to that effect. This special emphasis on consent, is believed to be necessary given the fundamental role of this requirement in medical practice in general and in human experimentation in particular. For as has been shown before, the requirement of the subject's consent is not only vital for the legal validity of experimentation but also fundamental for its legitimacy. Thus, acknowledging this fact, most of the international community's agreements relating to the use of human beings in medical research emphasised the requirement of consent. This emphasis was meant basically to protect the personal integrity of subjects and to remind investigators of the their nature as human beings who have a right to be free to decide as to whether to participate in human research. In these terms there seems to be no reason why in this country these principles should not be outlined in a piece of legislation as has

already been done in some other fields of research.

NOTES:

1-Applbaum, P.S., Lidz, C.W. & Meisel, A., Informed Consent: Legal Theory and Clinical Practice, Oxford, O.U.P., 1987, p 211.

2-This is true in both the U.S.A and the U.K, although the development of the doctrine of "informed consent" has been followed by subsequent statutory modification in the U.S.

3-German Reich, Circular of the Ministry of the Interior on Directives Concerning New Medical Treatments and Scientific Experiments on Man (1931). Translated in Int.Dig.Hth.Legisl. (Geneva)31, (1980) p 408-11, Howard-Jones, N., "Human Experimentation in Historical and Ethical Perspectives", 16 Soc. Sci. Med. (1982) pp 1429-48.

4-Bean, W.B., "Walter Reed and the Ordeal of Human Experiments", 51 Bulletin of the History of Medicine (1977) p 75-92.

5-Slater v. Baker & Staplton, 95 Eng. Rep 860 (K.B) 1767, 2 Wils. K.B 359 [1767].

6-2 Wils K.B [1767] at p 362.

7-See the previous discussion of the case in the chapter three, p 81.

8-See for example, Annas, G., Glantz, L., and Katz, B., Informed Consent to Human Experimentation: the Subject's Dilemma, Ballinger Publishing Comp., 1977, p 2.

9-Carpenter v. Blake, 60 Barb 488 (N.Y. Sup. Ct. 1871).

10-Jackson v. Burnham, 20 Colo.532, 39 P.577(1895) reversing Burnhan v. Jackson, 1 Colo. A 237, 28 P. 250 (1891).

11-20 Colo 552 [1895] p 536.

12-For further discussion see, Annas, Glantz and Katz, op.cit, p 3-4.

13-Brown v. Hughes, 94 Colo 295, 30 P. 2nd 259 (1934)

14-See 30 P.2nd [1934] pp 262-63.

15-Fotner v. Kock, 272. Mich.273, 261 N.W 762 [1935].

16-[1935] 261 N.W at p 765.

17-See for example, Faden, R. & Beauchamp, T., A History and Theory of Informed Consent, Oxford, O.U.P, 1986, p 191.

18-Fortner v. Kock, 272. Mich.273, 261 N.W 762 [1935].

19-For further discussion see, Curran, W.J., "Governmental Regulations of the Use of Human Subjects in Medical Research: the approach of two Federal Agencies" 98 Deadalus 542 [1969] pp 544-45.

20-Slammer v. Bd. of Regents, 262 App.Div 372, 29 N.Y.S 2nd 38 [1941], aff'd. 287 N.Y 359, 39 N.E 2nd 913 [1942].

21-39 N.E 2nd [1942] p 913.

22-Faden and Beauchamp, op.cit, p 153.

23-United States v. Karl Brandl et al, Trials of War Criminals under Control Council Law no 10.(Oct 1949-Apr 1949) vol 2. Washington D.C, U.S Governmental Printing Office.

24-For further description of the Nazi physicians' criminal acts see, Ivy, A.C., "Nazi War Crimes of a medical Nature" 33 Federation Bulletin 1947 pp 133-46, Shirer, W.L., The Rise and Fall of the Third Reich, Greenwhich, Conn, Fawcett, 1960, pp 1274-88, see also, Mant, "The Medical Services in the Concentration Camp of Ravensburck", 17 Med.Leg.Jour.99 (1950), Katz, J., Experimentation with Human Beings, Russell, Sage Foundation, 1972, pp 292-306.

25-United States v. Karl Brandl et al, No 10, Trials of War Criminals, vol 11 at p 181.

26-Principle one reads:

"The voluntary consent of the human subject is absolutely essential....the person involved....should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, and should have sufficient knowledge and comprehension of the element of the subject matter involved as to enable him to make an understanding and enlightened decision. This....requires that ....

there should be made known to him the nature , duration , and purpose of the experiment, the method and means by which is to be conducted, and the effects upon his health or person which may possibly come from his participation in the experiment".

27-Faden and Beauchamp, op.cit, p 155

28-Beecher, H.K., "Some fallacies and Errors in the Application of the Principle of Consent in Human Experimentation", 3 Clin. Pharmacolo.Ther. (1962) p 141-45

29-Frenkel, D.A., "Human Experimentation: Code of Ethics", 1 Leg. Med. Quarterly (1977) p 7-14. See also Bassiouni, M.C., Baffes, T.J. and Evrard, T.J., "An Appraisal of human Experimentation in International Law and Practice: The Need for International Regulation on Human Experimentation", 72 Jour. Criminal Law and Criminology (1981) p 1597-1666.

30-World Medical Association, Declaration of Helsinki: Recommandations guiding medical Doctors in Biomedical Research Involving Human Subjects. Adopted by the 18th World Medical Assembly, Helsinki, Finland 1964 [published in 271 N.E.J.M (1964) p 473. And as revised by the 29th World Medical Assembly, Tokyo, Japan 1975 as reprinted in Beauchamp, T.L., and Walters, L.W., (eds) Contemporary Issues in Bioethics, Dickenson Pub.Comp, 1978. The Declaration is of four parts: Introduction. I.Basic Principles. II. Medical research combined with professional care: clinical research. III. Non-therapeutic Biomedical Research involving human subjects: non-clinical biomedical research.(rev. ed.)

31-Medical Research Council, Responsibility in Investigations on Human Subjects in: Report of the Medical Research Council for the Year 1962-63, H.M.S.O, London (1964) pp 21-25, Applbaum, Lidz and Meisel, op.cit, p 214. See also British Medical Research Council: "Memorandum on Clinical In vestigations" in Ladimer, I., Newman,

R.W., (eds) Clinical Investigation in Medicine: Legal Ethical and Moral Aspects, Boston, Boston University Law-Medicine Institute 1963, pp 152-54.

32-supra cit.

33-Declaration of Helsinki (revised ed) 1975, (II, title).

34-Ibid (para.II.6).

35-Ibid (Introduction para.6). See chapter Five supra section II.

36-Ibid, (para.I.11).

37-bid, (para.II.5).

38-Declaration od Helsinki (1964 ed.) (II.1).

39-Swasey, Judith. P., "Protecting the Animal of Necessity: Limits to Inquiry in Clinical Investigation", 107 Deadalus 129 (1978) at p 133.

40-Woetzel, R.K., The Nuremberg Trials in International Law, London. Stevens & Sons Ltd.(2nd ed.,), 1962, p 222.

41-Id.

42-See the statement of Lord Henderson, "Parliamentary Debates" House of Lords, Official Report, vol 163. No 93 p 924 (July, 6. 1949).

43-See for example, Flick v. Johnson (1949) 174. F. 2nd 983, certiorari denied, 338 U.S 879 (1949).

44-Supra cit

45-Annas, Glantz and Katz, op.cit, p 8.

46-Kaimowitz v. Mich. Dept. Mental Health, Civil Action 73-19434-A.W (Wyne County, Mich. Cir. Ct. 1973).

47-See for the discussion of these cases, Annas, Glantz and Katz op.cit, chapter III.

48-Halushka v. University of Saskatchewan 52 W.W.R 608 (Saska. 1965), 53 D.L.R 2nd 436 [1966]

49-Baldor v. Rogers 81 Soc.2nd 658 (Fla. 1955).

50-Ibid at p 660.

51-Ibid at p 662. A similar language has been used in another case involving use of massive dosages of radiation to treat nonoperable cancer. The court said;

"In order for a physician to avoid liability by engaging in drastic or experimental tratment, which exceeds the bounds of estabilished medical standards, his patient must always be fully informed of the experimental nature of the treatment and of thje forseeable consequences of that treatment." Ahern v. Veterans Admin, 537 F. 2nd 1098 (10 Cir. 1976) at p 1102.

52-McHardy v. Dundee General Hospitals Board of Management, [1960] S.L.T (Notes) 19.

53-Ibid at p 19.

54-Id.

55-Fiorentino v. Wenger 26 App. Div. 2nd 693, 272 N.Y.S end 557 (1966).

56-53272 N.Y.S 2nd 557 (S.D Texas 1972) at p 559.

57-Ibid at p 559.

58-Karp v. Cooley 349 F. Supp 827 (S.D Texas 1972), Karp v. Cooley, 493 F.2nd 408 (5th Cir. 1974).

59-The second document reads as follows:

"I, Haskell Karp, request and authorize Dr. Denton Cooley and such other surgeons as he may designate, to perform upon me, in St. Luke's Episcopal Hospital of Houston, Texas, cardiac surgery for advance cardiac decompensation and myocardial insufficiency as a result of numerous coronary occlusions. The risk of the surgery has been explained to me. In the event cardiac function can not be restored by excision of destroyed heart muscle and plastic reconstruction of the ventricle and death seems to be imminent, I authorize Dr.Cooley and his staff to remove my diseased heart and insert a mechanical cardiac substitute. I understand that this mecanical device will not be permanent and ultimately will require replacemnet by a heart transplant. I realize that this device has been tested in the laboratory but has not been used to sustain a human being and that no assurance of success can be made. I expect the surgeons to exercise every effort to preserve my life through

any of these means. No assurance has been made by anyone as to the results that may be obtained." (emphasis added) 349 F. Supp 827 S.D Texas (1972) at p 831.

60-493 F. 2nd 408 (5th Cir. 1974) at p 423.

61-Annas, Glantz and Katz, op.cit, p 13.

62-Ibid p 13-14.

63-Cited by Annas et al, op.cit, p 14.

64-National Heart and Lung Institute Code (August 7, 1974).

65-S.3 para.11 reads, in part;

The device is to be used only in a situation in which it offers at least as likely benefit as any known accepted technique or any experimental technique which is available for clinical trial in the same setting by the same group.

There must be experimental evidence from laboratory animal studies of beneficial effect.

Definition criteria for patient selection must be included in the investigation protocol.

The approval of local institutional research committee and other appropriate committees and conformity to the Institutional Guide to D.H.E.W policy on Protection of Human Subjects is required.

Prior to the clinical use, the complete research protocol must be approved by N.H.L.I.

66-Committee on Ethics of the American Heart Association, "Ethical Considerations of the Left Ventricular Assist Device" 235 J.A.M.A 823 (Feb. 23, 1976).

67-This is because the committee reasoned that;

"a strong mutual dependency" is likely to develop between the patient and the treating physician, and that the patient or family "may already have lost their individuality to consent meaningfully." p 824.

68-Committee on Ethics of the American Heart Association, loc.cit, at p 824.

69-Halushka v. University of Kaskatchewan, supra.cit.

70-See for example, Brazier, M., Medicine, Patients and the Law, Harmondsworths, Penguin Books, 1987, p 287.

71-Halushka v. University of Kaskatchewan, supra.cit, at p 438.

72-Ibid pp 443-44.

73-Ibid p 444

74-See Katz, J., Experimentation with Human Beings, op.cit, Chapter III.

75-Report of the Regents Committee on Discipline, "In the matter of Southam and Mandel", (Nos 158, 159 undated opinion).

76-Ibid p 5-6, also in Katz, op.cit, p 60.

77-Ibid p 7-8.

78-Ibid p 8.

79-See for example, Faden and Beauchamp, op.cit, chapters 5 and 6., see also, Applbaum, Lidz and Meisel, op.cit, chapter 11, p 211.

80-The U.S.A's Department of Health and Human Services (D.H.H.S), 45 Code of Federal Regulation, Protection of Human Subjects, [1984], § 46.103 (c).

81-Ibid, § 46.116 (a).

82-namely, applbaum, Lidz and Meisel, loc.cit.

83-Ibid p 232.

84-Id.

85-Applbaum, P.S., Roth, L.H., Lidz, C.W., "The therapeutic Misconception: Informed Consent in Psychiatric Research", 5 Int. J. Law. Psychiatry (1982) pp 319-29, see also, Gray, B.M., Cooke, R.A. & Tannenbaum, A.S., "Research Involving Human Subjects", 201 Science (978) pp 1094-1101.

86-Brazier, M., op.cit, p 294.

87-Ibid, p 286.

88-Mclean, S.A.M., Disclosure of Information, Consent to Medical treatment and the Law, Ph.D Thesis, Glasgow University, 1987, p 354.

89-or "unpractised or unaccepted treatment", Meyers, D., The Human Body and The Law, Edinburgh, E.U.P, 1970, at p 73.

90-Hunter v. Hanley, S.C 200 [1955]

91-at p. 206.

92-McLean, S.A.M., (1987), op.cit, p 359.

93-Ibid p 360.

94-Ibid.

95-notably, Mason, J.K. & McCall Smith, R.A., Law and Medical Ethics, London, Buttersworths, 1987, p 265.

96-Bolam v. Friern.

97-Sidaway v.Bethlem Hospital Governors & Ors [1984] 1 All E.R 1018 (C.A), [1985] 1 All E.R 643 (H.L).

98-Mason and McCall Smith, op.cit, at p 265.

99-Supra cit.

100-Brazier, M., op.cit, p 287

101-The Leading case on this issue is the Canadian case of Halushka v. University of Saskatchewan, Supra cit, for discussion, see p 211 above.

102-See, for example, McLean, (1987), op.cit, p 363, Brazier, op.cit, p 292., Mason and McCall Smith, op.cit, p 265.

103-Op.cit.

104-Ibid at p 292-93.

105-op.cit.

106-Ibid at p 265.

107-See, for example, McLean, (1987), op.cit, p 363, Brazier, op.cit, p 292., Mason and McCall Smith, op.cit, p 265.

108-Report of Royal Commission on Civil Liability and Compensation for Personal Injury.(Cmnd 7054/1978.)

109-Ibid para. 1341.

CHAPTER SEVEN

CONCLUSIONS

The main point which was argued in this discussion is that patient as a human being when he or she is of sound mind and adult years has no less rights in the practice of medicine than healthy person in other circumstances. He or she must be treated as an autonomous person when he or she has the capacity to decide about his or her own future in respect of his or her health care.

It was argued that the patient has the right to consent to any medical intervention either in therapy or experimentation and that this right provides him or her with a sufficient protection of his or her autonomy or self-determination.

In order that consent have this effect it must be based on a sufficient disclosure of information, since it is this element which plays a central and fundamental role both in facilitating his or her autonomy and in the morality of the medical enterprise. However, the lack of capacity which may affect some groups namely children, the mentally handicapped adult persons, and the mentally ill may justify the intervention of other persons so that their consent is taken by proxy. But when the capacity of the individual is not in doubt, he or she is the only person who can accept or reject the medical treatment based on a comprehensible and reasonable disclosure of information.

As a general rule, then, before a treatment may be administered, whether it be therapeutic or experimental it is necessary for the physician to obtain the consent of his or her patient. However, if the circumstances are such that they demand immediate attention for the preservation of the patient's life, limb or health, the doctor may

proceed with the treatment without consent if the person is not in a position to consent to or refuse treatment.

It was also argued that where it is appropriate to obtain consent, the physician is legally asked to disclose to his or her patient the relevant information for him or her to make a rational decision about whether to consent to the recommended treatment. Such a requirement is both vital and fundamental to the patient, for as it was already argued one can not legally consent to the invasion of one's own body if one is unaware of the nature and consequences of the invasion. Legally speaking it is also important for the doctor to obtain a valid consent since it is the patient's consent which renders permissible what would otherwise be assault or battery.

With respect to information disclosure, this must be made in simple language in order to assure that the patient understands it. It must also be free from any misrepresentation of facts or of the nature of the procedure, for such may invalidate the patient's consent if he or she does authorize the performance of a given treatment under such circumstances.

It should be noted, however, that the doctor is not responsible for the possible inability of the patient to assimilate the information disclosed. It is hard, one must admit, to reconcile this idea with that which suggests that the patient's consent must stem from knowledge and understanding. But the fact that the patient can hardly comprehend the information, does not exonerate the doctor from his or her duty to disclose information. In such circumstances the physician is asked to make some effort to make himself or herself understood by the patient, for it is often argued that if the information is presented in everyday language it can be grasped by most patients.

It was shown that in court decisions whether here in Britain or elsewhere self-determination has been the principle most called upon to justify the physician's obligation to seek the patient's 'informed', valid, or real consent. The law's protection for this fundamental right has been tempered, however, with the shift to the negligence format, and the grounding of the physician's obligation to disclose information on his or her general obligation of care owed to the patient rather than on the patient's right to know.

Moreover, because of other concerns that courts had to confront, sometimes self-determination had been tempered or even ignored. Very often these concerns or interests were beneficence-based considerations of patient welfare. Therapeutic objects, for example, courts believed had to prevail over the patient's right to decide what should be done with his or her own body. In other instances, the law had been turned away from its basic role of protecting the patient's right to self-decide because of the mechanics and pragmatic constraints that the legal process contains, e.g the causation requirement in negligence. As has been explained before, in order to recover damages, the patient has to provide a proof of abuse only after the event takes place, and that proof has to satisfy the the courtroom's procedural rules.

Legal Position:

So far in Britain, the law recognizes that the person has a right to choose what shall be done with his or her own body, and therefore he or she must consent to medical treatment otherwise it will be trespass to the person. It is also established that consent to the nature of the procedure is enough to preclude an action in battery.

Failure to provide the patient with sufficient information to make a rational and 'informed' decision as to whether to agree to the proposed treatment, must be litigated in negligence. One British court reasoned that justice required that "in order to vitiate the reality of consent there must be a greater failure of communication between doctor and patient than that involved in a breach of duty if the claim is based on negligence."[1] That is the doctor's duty to inform stems from his or her general duty of care due to the patient, but not from the patient's right to be informed. Hence, the doctor can not be held liable in negligence if he or she fails to inform of particular risks as long as he or she acts in accordance with a practice accepted as proper by a responsible body of medical men skilled in the particular art. That the principle also applies as a standard for information disclosure, was confirmed in the decision of the House of Lords in the case of *Sidaway*[2]. However, according to the House of Lords, the court will retain its judicial right to intervene, if it comes to the conclusion that the disclosure of a particular risk is so obviously necessary to make a rational choice that no prudent doctor would omit to disclose.

In these terms, it can be submitted that the principle of full information disclosure has no place in British law. In fact, it has already been pointed out by one writer[3] that the adoption of such principle would depend on the judicial policy of the country. In the United States 'informed consent' was adopted as a judicial ruse to ensure compensation for the greatest number of those who may suffer damages in medical treatment, which led, among other things, to the practice of defensive medicine.

It is the fear of developing a similar crisis in this country which led British courts to adopt the professional standard in favour

of that of 'informed consent'[4].

Most scholars stressed the importance of the patient's comprehension as related to a full information disclosure principle.[5] As has been pointed out, what is confusing in the whole issue is the use of the term 'informed' consent which has been interpreted differently. Even in the U.S. where the doctrine of informed consent first appeared and developed, the majority jurisdictions opted for the professional standard instead of that of the 'prudent patient'. Perhaps the first thing to do, as Mason[6] suggested is to abandon the term 'informed' in favour of 'rational' or 'valid'.

In any event, as things stand at present, it seems that the controversy that characterized medical transactions over the standard of information disclosure was over following the decision of the House of Lords in *Sidaway*.[7] The decision as to what is to be disclosed is a matter of medical judgement, and the doctor fulfills this duty if he or she acts in accordance with a practice accepted by a responsible body of the medical profession. Up to now at least two cases decided after *Sidaway* have confirmed this view.[8]

In the experimental setting, however, the status of consent is not as clear as in therapy.

Ethically, as in therapy, the fundamentally crucial aspect of all experimentation is the right of the human subject whether he or she is patient or volunteer to make 'informed' and rational decisions about his or her own body. It is the observance of this ethical and legal requirement that makes any benefit obtained from experimentation meaningful. As has been said, the investigator's role is secondary to the interest that the human subject has in his or her own autonomy. The subject's decision to take part in experimentation can be

motivated by a self-interest in the cure or by altruism, but still remains a rational decision.

Whatever the subject's motives are, however, his or her interest in not being harmed as a result of experimentation must prevail over the interest of the community as a whole in acquiring new knowledge or developing new therapies. In these terms, it can be said that different interests are in conflict and, therefore, a balance is necessary that allows for the continuation of all types of experiments which are likely to benefit society without neglecting the basic human rights of the individual subject.

The design of the experiment, in particular, must be made in such a way as to ensure that the subject is exposed to minimum risks, and that the experimentation is not carried out unless there is a real need to investigate or evaluate new or old therapies or techniques.

Since many experiments may or do actually benefit the community, a fact which has been recognised by the international community which tacitly allowed the conduct of human research by the promulgation of codes of ethics, it is admittedly necessary that human experimentation continue. On the other hand, a meaningful continuation of this enterprise depends, to a great extent, upon the efficiency of the mechanisms of control which are in use.

In order to accommodate the conflicting interests of all those involved, special mechanisms of control are needed, particularly, when experiments involve subjects from the vulnerable groups. For experimentation may need to be carried out on the otherwise vulnerable. Children, for example, may be needed as subjects in certain experiments that deal with specific diseases that affect only children. In such cases special dispositions are needed for the conduct and control of these experiments, in particular, non-clinical

ones. The obtaining of consent in these circumstances is more problematic than is the case when the subject is an adult and rational person. Experimentation with children, for example, may be justified when it is the only alternative to find a cure for the patient. Thus the parent or the guardian can legally authorise such intervention on the basis that he or she is acting in the best interests of the child. When the experiment is non-therapeutic, however, such authorisation can not be easily justified, since arguably, as far as the child's condition is concerned, there is no ground on which to base such authorisation.

This is a mere example of the complexity of the issue. In such cases the intervention of the law is necessary to govern the issue. In the U.S.A, for example, since the early sixties a system of regulation by statutes and legislation has been erected to control human research including the fundamental requirement of consent. In this respect, there are specific dispositions relating to the issue of consent which have gone as far as specifying the information that must be disclosed to the subject and how to secure his or her acquiescence.

In the United Kingdom few fields of experimentation have been sanctioned by specific legislation. At the moment only research with new drugs which is controlled by legislation. Until further dispositions are promulgated, its seems that the medical profession will continue to control medical research through its own administrative bodies. In this respect, a review of the constitution and function of Research Ethical Committees is recommended, and the adoption of a policy which allows for higher percentage of lay membership in R.E.C.s is particularly urged.

The role of the law at the moment is said to be limited to intervening only when disasters occur. Courts can only monitor the

research enterprise in a retroactive way and only after disasters occur. In addition a grieved subject can hardly succeed in receiving compensation. For in the absence of specific dispositions on this issue the subject has to go through the negligence action with all its drawbacks.

The *Sidaway* test, it is said, is likely to be also applied in clinical innovation. One would add that if such an approach is to be followed, the assessment of standard practice must be made according to Declaration of Helsinki's guidelines on the issue. But, one must reiterate the view that it is only through a proper definition of the principles governing the research enterprise, including those relating to consent and compensation for personal injury, that experimentation becomes moral.

Thus, it is suggested that regulation should take the form of a legal framework that defines the general principles and guidelines that govern the conduct of human research, according to the guidelines set by the international community in the Declaration of Helsinki, and other international agreements.

In this respect, a special emphasis should be attributed to the issue of consent given the lack of precision which surrounds its current status. The writer believes that the importance of this ethical and legal requirement which basically lies in protecting the human subject dictates that consent be regulated efficiently in order to achieve the purpose which it has been created for.

NOTES:

1-Chatterton v. Gerson [1981] 1 All E.R 257, at p 265.

2-Sidaway v.Bethlem Hospital Governors & Ors [1984] 1 All E.R 1018 (C.A), [1985] 1 All E.R 643 (H.L).

3-See for example, Robertson, G., "Consent to medical treatment", 91 L.Q.R (1981). p 102.

4-First enunciated in Canterbury v. Spence.464 F.2nd 772 (D.C Ci. 1972)

5-See, for example, Robertson, loc.cit, Mason, J.K., "Consent to Medical Treatment", (1986) Sco.L.A.G. p.73.

6-op.cit, at p 76.

7-Supra.cit

8-See, for example, Gold V. Haringey H.A, The Times 17 June [1986], 1 F.L.R 125 [1987], Blyth v. Bloomsbury Health Authority , The Times, 24 May 1985 but reversed at time of going to press, The Times, 11 February [1987].

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