UNIVERSITY OF NAIROBI

INFORMED CONSENT LAW IN LIGHT OF MODERN MEDICAL PRACTICE, RESEARCH AND TECHNOLOGY: A CASE FOR LEGISLATION IN KENYA

A Research Paper submitted to the Faculty of Law in Partial Fulfillment of the requirements for the Master of Laws Degree

By

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2005
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Declaration

I, Mark Joseph Obuya hereby declare that this Paper is my original work and has not been submitted either in part or in whole and is not currently being submitted for a degree in any other University.

Signed: ..................................

Date: ........................................

24th November, 2005

This Project Paper has been submitted for examination with my approval as a University of Nairobi Supervisor.

Signed: ..................................

Date: ........................................

24/11/05

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Lastly, for the rhythm and energy that kept me going, I am grateful to Kayamba Africa at Pan Africa Hotel, Nairobi.
Dedication

This work is dedicated to my late mother, Esther, who succumbed to cancer and died on 9th September 2001 and to all victims of medical negligence. To my father Daniel and my wife Eleanor and our four issues; Angela, Joe, Kevin, Raymond and to Vicky and Denis for their patience despite the neglect suffered during the writing of this paper.
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<td>CIOMS</td>
<td>Council for International Organisation of Medical Sciences</td>
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INFORMED CONSENT LAW IN LIGHT OF MODERN MEDICAL PRACTICE, RESEARCH AND TECHNOLOGY: A CASE FOR LEGISLATION IN KENYA

INTRODUCTION

The doctrine of informed consent is the cornerstone of modern medical jurisprudence. Although the need for ordinary consent to treatment is old, informed consent as defined below, arose after World War II from the shocking revelation at the Nuremberg Trials that Nazi doctors were carrying out medical experiments on unwilling prisoners in the Nazi Concentration Camps.¹

It can be shown that, as a principle of law dealing with a physician’s and researcher’s fiducial duties to their patients or research subjects, the application of the doctrine of informed consent tends to shift from one concern to another. For example, the doctrine may be applied to guard against unnecessary or inappropriate treatment of patients, or applied to guard against unreasonable denial of treatment based on considerations of issues such as cost cutting methods by medical care givers and concerns regarding the regulation of the removal, use and disposal of human tissue.

As distinguished from ordinary consent, “informed consent”, is used throughout this paper as a doctrine which aims at ensuring that full disclosure of the scope, nature and the risks that will be encountered in the course of a proposed treatment or proposed research activity, is provided to the patient or research

subject to form the basis for their agreement to proceed with the treatment or to participate in the research.

It has however, been one of the most misunderstood doctrines in medical law and medical research involving humans, sometimes driving a wedge between patients and subjects of research on the one hand and medical researchers and physicians on the other.

This paper is therefore intended to review the history of informed consent and to discuss the different standards governing informed consent as distinguished from ordinary consent, and the legal implications for its application in the conduct of research, developments in medical treatment and technology in Kenya.

The standards governing the application of informed consent reflect the conflict between legal ideals of medical care, medical research and the realities. Patient advocates and many physicians view informed consent as a way of empowering patients or research subjects, thereby making them equal partners in the therapeutic relationship and or the subject of research. It may be briefly observed that the doctrine of informed consent requires that patients or research subjects be informed of any material or significant risks in the proposed treatment or research, any alternatives to it and the risks that will be incurred by doing nothing. This distinguishes it from ordinary consent where consent may be implied. For example, where a patient holds out an arm for an injection.

As noted earlier, informed consent was not a topic of general interest until the War Crimes Trials at Nuremberg shocked the world medical community with the revelations about the experiments carried out by physicians in the death camps.
Blurring the line between experimentation and torture, these experiments moved the discussion of consent to medical care from the philosophical to the practical. Many physicians belief that informed consent is a creature of legal fiat, no it is not, it is the natural societal response to the demystification of medicine.

As medicine has moved from the "Miti Shamba" or (Shaman) tent to the research laboratory, it has adopted the cloak of logical decision-making. Therefore, the natural response is the assumption by the lay public that, given enough information, they will rationally make their own medical decisions. This was explicitly captured in the classic statement of justice Cardozo's opinion on the physician's duty to get his patients consent in *Schoendorff-V-Society of New York Hospital* when he stated:

Every human being of adult years 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 patients consent commits an assault for which he is liable for damages. This is true except in cases of emergency, where the patient is unconscious and where it is necessary to operate before consent can be obtained.

Lack of adequate legislation on informed consent in Kenya has affected families and society in a number of ways. Firstly, the knowledge, often, some years later that treatment was given or denied, organs or tissue were removed from someone close to them without consent has brought profound sorrow to many families. Secondly, the question of medical research is controversial, because it offers an opportunity for fraudulent medical scientists who are in for profit-ventures to violate laws leaving their patients feeling cheated. We will discuss the HIV/AIDS

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2 "Miti Shamba" here means a traditional herbalist
3 A Shaman is a witchdoctor or a priest who claims to communicate to the Gods about treatment
4 *Schoendorff-v-Society of New York Hospital, 105 NE 92 (NY 1914).*
research on the “Majengo Sex Workers” and children from the Nyumbani Home for AIDS Orphans. Here, we will survey the historical and current settings of the law on consent and its implications on the use of human tissue and the ways in which the law and society have responded.

We will discuss the American legal case of *Moore-v-Regents of the University of California* as it raises a number of ethical and legal issues, which are relevant to the doctrine of informed consent. Some of these concerns include; whether human tissue is property and whether there are unethical uses of human tissue.

It is with these concerns in mind that we argue that there is need for a specific legislation on health care consent and a broad revision of the Human Tissue Act, The Anatomy Act among other legislation that inform consent. The review must respond to the legitimate expectations and rights of patients, research subjects and their families.

We take the view that if this is done it will:

i) Ensure that no treatment or research involving human subjects is done without consent

ii) Ensure that no human bodies, body parts, organs or tissue will be taken without the consent of relatives, patients or research subjects.

iii) Prevent a recurrence of distress caused by retention of tissue and organs without proper consent by providing safeguards and penalties.

iv) Help improve public confidence so that people will be willing to agree to valuable uses of tissue and organs like research and transplantation.

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5 *Moore-v-Regents of the University of California* (1990) 793P 2d 479
6 The Human Tissue Act CAP 252 Laws of Kenya
7 The Anatomy Act Cap 249 Laws of Kenya
v) Provide rules with respect to consent to treatment that apply consistently in all settings.

vi) Will ensure that there is freedom of choice by the patient and self determination.

It should be noted that because of limitations, this paper is specific to informed consent for medical treatment, research for medical treatment, research involving human subjects and the removal, use and disposal of human tissue, and the following areas have not therefore been included;

i) The use of personal information

ii) Transplantation and sale of organs

iii) Abortion

iv) Euthanasia

v) Use of human tissue as property for commercial purposes.

STATEMENT OF THE PROBLEM

The laws of Kenya dealing with the question of consent for treatment and biomedical research and the issues concerning the removal, use and storage of human tissue are outdated. They need to be reviewed and adjusted in order to take into account the recent advances in biological and medical research which have developed alternative treatments to illnesses and therefore permit the use of more than one method of treating an illness and options for multiple uses of human tissues which may be removed, but only with the informed consent of the patients or research objects involved.
The rapid advances in technology and in the biological, and medical research has resulted in more options for treatment of illnesses, including the removal, use and storage of human tissues, which in turn has also brought with it certain fundamental and ethical concerns (not to mention religious ones) that must be fully addressed by the law.

At present, there is great uncertainty about how courts will resolve disputes between patients and physicians where there is no informed consent and disputes between human sources of tissue and tissue users. This is detrimental both to the treatment of patients and the development of medicine.

**RESEARCH QUESTIONS**

From the above introduction it clearly emerges that the doctrine of informed consent is the cornerstone of modern medical jurisprudence. However, legislation and regulation on consent has not kept pace with the rapidly advancing scientific and medical developments. There are fundamental ethical and legal questions that beg for answers. For example questions about consent requirements for medical treatment and uses of human tissue include:

i) What are the applicable legal principles for consent to medical treatment and research involving human beings

ii) Are there any uses of human tissues, which are ethically unacceptable even if the donors freely consent to such uses?
iii) What should be the procedural requirements for informed consent to safeguard the rights of patients who seek treatment and the rights of persons from whom tissue is removed?

This paper therefore seeks to examine the law on consent, and how it has responded to these concerns in view of advancement in medical technology and to examine whether the common law on consent, the Human Tissue Act and other regulations have kept pace with the advancement in science and medical development.

THEORETICAL/CONCEPTUAL FRAMEWORK

It is a general legal and ethical principle that valid consent be obtained before starting treatment or physical investigation on a patient or research on human persons. This principle reflects the right of patients to determine what happens to their own bodies and is a fundamental part of the right of self-determination and the autonomy of the individual. This is what the doctrine of informed consent sets out to achieve.

As a pure legal issue, forcing treatment on an unwilling person is no different from attacking that person with a knife. The legal term for a harmful or offensive touching without permission is a battery. Battery is a criminal offence, and it can also be the basis of a civil lawsuit. The key element of battery is that the touching is unauthorized, not that it is intended to harm the person.

Battery is a legal threat in three situations: If the patient has been lied to about the treatment or there is other fraud in informed consent, then the entire
consent is invalid. The second one is when the patient is incompetent to consent and receives improper care. The third is where the patient has refused care and the care is forced on him or her, in an involuntary setting. Public concern has also been raised over the use of human tissue. The issues raised are over consent to treatment, consent to research and the relationships between doctors and their patients and that of researchers and their research subjects.

The subject is complex; the wider uses of tissue are presenting more and more difficult problems of ethics and the law: There are for example, the ethical implications of making human tissue available for clinical treatment and research. Lawyers are still discussing a cause célébre – the case of Moore-V-Regents of the University of California, which raised key questions of consent and ownership.

It is against this background that we argue for specific legislation on healthcare consent and review of the Human Tissue Act to reflect current technological developments in medicine.

LITERATURE REVIEW

In Kenya, there is no specific legislation dealing with health care consent and consent for medical research on humans. This has largely been left to the dictates of common law. Some of the new methods of treating patients, new research and commercial uses of human tissue have raised a number of issues, some of ethics and some of law. These issues are novel, and little has been written about them. They are also very complex and it is not surprising that there is no single body of law and policy from which conclusive answers can be drawn.
However, it is worthy of note that the question of informed consent for medical treatment or research is topical and has gained increasing significance in the works of different authors and deliberations of various international and national professional bodies concerned with healthcare and biomedical research.

McLean\(^8\) observes that the development of rules which require patients to agree in meaningful terms to recommended treatment is designed to achieve a number of goals. Most importantly these rules were intended to secure the right of the individual to act in an autonomous or self determining manner as well as to impose on Physicians an obligation to make appropriate disclosure of relevant information to the individual, in order that the exercise of autonomy can be meaningful. The rules also provide protection for doctors by rendering lawful what could otherwise amount to a trespass to the person.

The Department of Health of the United Kingdom has issued guidelines\(^9\) on the law concerning consent to treatment and physical interventions on patients. Guidance is provided on the legal requirements for obtaining valid consent and on the situations where the law recognizes exceptions to the common law requirement to obtain consent. These guidelines on consent to treatment addresses a population that is literate. In Kenya the population is largely illiterate and this has to be taken into account when developing a legal framework for consent to treatment in Kenya. However, we will examine these guidelines and see whether we can borrow from them with the view of creating a new legal framework on informed consent that will guide healthcare professionals in Kenya.


The Nuffield Council on Bioethics\textsuperscript{10} 1995 has issued a report which deals with the ethical and associated legal questions raised by the medical and scientific uses of human tissue. This report also addresses issues of concern to us, notably consent to treatment and the relationship between doctors and patients. An examination of this report reveals that the law must constantly be reviewed to take into account developments in medicine and biomedical research, so that public concerns regarding treatment, research and the removal, use, storage and disposal of human tissue are addressed, and where needed, the formulation of new guidelines by the appropriate regulatory body.

Jones\textsuperscript{11} observes that medical research is controversial because of the abuses that can result. This range from the medical experiments that were conducted by the Nazis to the Tuskegee syphilis experiment conducted by the United States Public Health Service on poor black people without their consent in Tuskegee, Alabama. They were even not informed of their disease and denied treatment even after treatment was found in 1947. He argues that this was done because they were vulnerable, poor and that they could easily be manipulated. The purpose of our study is therefore to find out what role the doctrine of informed consent and the law can play to avoid such incidents. We shall compare this incidents with the AIDS studies that were done in Kenya involving the Majengo Sex Workers and the Nyumbani AIDS Orphans and identify the lacuna in the law and recommend how such gaps can be sealed to protect the marginalized. This is necessary because the law is the basis of social justice. It has the function of curbing excesses of the


market and protecting the rights of those who are vulnerable, especially the poor
and the under privileged.

Wasserman "et al" have argued that the most commonly recognized conflict of interest in healthcare is in the treatment of family members by doctors. This creates a problem for the doctrine of informed consent in that objectivity is impossible when one is treating a patient who is emotionally attached to the doctor. Physicians therefore treat their colleagues families without charge. This helps and ensures that information is not withheld and therefore objective decision making is done without any hindrance. This is critical for the doctrine of informed consent.

Mason and McCall Smith have argued that as a general rule, medical treatment even of a minor nature, should not proceed unless the doctor has first obtained the patients consent. The principle of requiring consent applies in the majority of cases but there are certain circumstances in which a doctor may be entitled to proceed without consent, for example, when the patient's balance of mind is disturbed, the patient is incapable of giving consent, or is a minor.

We have noted that most disputes as to consent arise in the context of an alleged non disclosure of the risks involved in a particular treatment or research involving human participants. In this paper we argue that the laws of Kenya are outdated and need to be reviewed to ensure that no person is exposed to a risk of damage or injury unless they have agreed to the risk.

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Oruka\textsuperscript{14} has observed that the medical profession is guided by principles beyond the ethics of common sense. The principles of medical ethics are principles which spell out the ethical rules which doctors or patients and all reasonable people in society should accept as criteria for any rational and moral decisions made about the treatment administered to the sick. These principles have certain characteristics and suggest that the patient be informed of the risks of the treatment that he is about to undergo and his consent obtained, and this is relevant to our study of the doctrine of informed consent.

Havighurst, Blumstein and Brennan\textsuperscript{15} have noted that the movement to enforce and expand the disclosure obligations of physicians reflects increasing judicial concern about the imbalance of power between physicians and patients and about the conflict of interests that physicians often face in making clinical choices. This range from issues of patient choice, the availability of alternative therapies that must be disclosed and the influence of managed care plans that encourage physicians to withhold beneficial treatments to patients if such treatments are costly. This raises a number of concerns for the doctrine of informed consent, such as whether the withholding of beneficial treatment from patients is actionable and justified.

In Kenya The Medical Practitioners and Dentists Board of Kenya which is established under Section 4 of The Medical Practitioners and Dentists Act CAP 253 has issued “The Code of Professional Conduct and Discipline”\textsuperscript{16} which requires

\textsuperscript{14} Oruka, H.O. ‘Ethics’ (1\textsuperscript{st} Edition), (Nairobi University Press, 1990).

\textsuperscript{15} Havighurst, C.S, Blumstein J.F. and Brennan T.A. “Health Care Law and Policy” (2\textsuperscript{nd} Edition), (New York: Foundation Press, 1998),1025

\textsuperscript{16} The Code of Professional Conduct and Discipline (5\textsuperscript{th} Edition) MPDB: Circular No. 4/79), 24-25

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doctors to obtain consent where possible before treating any patient. It does not make it mandatory. The practice in this area has largely been left to common law. Because of recent developments in the medical field, common law has been left behind and has not kept pace with the developments and in some cases the legal position has been rather unclear.

The Public Health Act\textsuperscript{17} and The Mental Health Act\textsuperscript{18} also deal with the subject of consent but in a very narrow manner as we shall see later in this paper.

The National Council for Science and Technology (NCST) which is set up under the Science and Technology Act\textsuperscript{19} that has issued guidelines for the ethical conduct of biomedical research involving humans in Kenya.\textsuperscript{20} As we shall see, the problem with these guidelines is that they are based on western concepts and may not be appropriate to local circumstances. These guidelines have drawn very heavily from international guidance for the conduct of research involving humans, namely the Declaration of Helsinki 1964 which has been widely adopted throughout the world. However, taking into account the transitional nature of research, and the growing incident of research involving clinical trials of medicines and vaccines, particularly following the emergency of HIV and AIDS, further revisions are necessary.

As for human tissue and body parts the two main statutes governing the removal, retention and use of human organs and tissue are the Human Tissue Act\textsuperscript{21} and the Anatomy Act.\textsuperscript{22} The Human Tissue Act has the following purposes:-

\textsuperscript{17} The Public Health Act CAP 242 Law of Kenya
\textsuperscript{18} The Mental Health Act CAP 248 Laws of Kenya
\textsuperscript{19} The Science and Technology Act CAP 250 Laws of Kenya
\textsuperscript{20} Guidelines for the Ethical Conduct of Biomedical Research involving Human Subjects in Kenya, (NCST No. 45, 2004)
\textsuperscript{21} The Human Tissue Act CAP 252 Laws of Kenya (Revised Edition) 1967
\textsuperscript{22} 13
...to make provision with respect to the use of parts of bodies of deceased persons for therapeutic purposes and purposes of medical education and research; and for matters connected therewith and incidental thereto. (Preamble)

Under Section 2(2) of this Act the person “lawfully in possession” of the body may, unless he has reasons to believe that a request was subsequently withdrawn, authorise the removal from the body of any part. In effect therefore, no specific consent is required to remove a tissue or organ from a dead body. This has resulted in body parts being removed from the dead without consent. Another notable feature of the Human Tissue Act is the absence of any regulatory framework or of any penalties for non-compliance.

We will examine two primary international guidelines that govern the conduct of medical research on humans, namely the Nuremberg Code and the Declaration of Helsinki and their relevance to the doctrine of informed consent.

We will also examine other international Conventions and Declarations that are relevant in this area. For example the European Convention on Human Rights and for comparative purposes we shall also review legislation in other countries notably the United States of America and the United Kingdom. For example in the United Kingdom we shall examine the consent guidelines issued by the Department of Health.

The essence of discussing what happens in other jurisdictions is to draw a parallel to our own laws and show the trend and therefore the need to review our laws relating to consent for treatment and research.

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22 The Anatomy Act CAP 249 Laws of Kenya
23 War Crimes Tribunal at Nuremberg 1947
24 World Medical Association 1964
25 Department of Health; Reference Guide to Consent for Examination or Treatment (2002)
Some of the new research and commercial uses of human biological materials have raised legal and ethical questions regarding the acquisition of bodily substances. These issues are novel, and little has been written about them. They are also extremely complex, and thus it is not surprising that there is no single body of law, policy, or ethics from which indisputable conclusions can be drawn. For example, nineteenth century legal cases concerned with body snatching established the principle that a body cannot be considered property. Does this legal principle apply equally to parts of the body, which may have been removed from a living person?

In which circumstances can explicit consent under common law be waived in the case of removal of gametes? Can the Human Tissue Act as currently enacted deal adequately with concerns involving human tissues, when it does not even provide for penalties and compensation. The area is pregnant, complicated and confused, with many uncertainties about the legal basis of the different uses of human tissue. We have examined the current state of the law in some detail that is the common law, The Science and Technology Act, the Human Tissue Act, the Anatomy Act and other related regulations and note that there are areas of uncertainty. The review will demonstrate that the current law is inadequate and outdated. Our contribution is to suggest ways in which the areas of uncertainty may be clarified.

26 The famous example is that of William Burke and William Hare who practiced their trade as body snatchers or resurrectionists in Edinburgh in the United Kingdom in the nineteenth Century.
OBJECTIVES OF THE RESEARCH

The main objective of this research is (i) To show the need for healthcare consent legislation in Kenya, and (ii) To identify the legal lacuna in the Human Tissue Act and suggest ways of filling the gaps in view of recent developments in biological and medical research.

HYPOTHESIS

The enactment of healthcare consent legislation is necessary for good medical practice in Kenya and reviewing of the Human Tissue Act, is necessary and will ensure that no human bodies, body parts, organs or tissue will be taken without the consent of patients during treatment or research involving human beings.

RESEARCH METHODOLOGY

In conducting this research the library will form a major source of material, we shall also interview selected medical and legal experts in this field and use the internet in searching for solutions to the concerns raised by the public, patients and research subjects.

CHAPTER BREAKDOWN

Chapter one provides the background to this study. We will survey the historical and current settings in which questions of informed consent to treatment have arisen and how the law and society have responded. We will also discuss the disclosure standards of such consent.

In Chapter two we examine the requirements that must be met for genuine consent to be obtained. We will discuss the various factors that affect capacity.
will also discuss and examine what is meant by competence and the competence of various categories of people to give healthcare consent. We will also examine here the various forms of consent and how consent can be documented.

In Chapter three we will examine the doctrine of informed consent in relation to research involving human subjects. We will discuss the law, regulations and international guidelines and the concerns that they raise.

In Chapter four we deal separately with the issues relating to the removal, use and disposal of human tissue. This is because some new research and commercial uses of human biological materials raise concerns that are novel, complex and little has been written about them. We survey the historical and current settings in which questions about the uses of human tissue have arisen, we will discuss the legal and ethical concerns and the ways in which the law and society in general have responded. Issues raising concern here include, informed consent, trafficking in human organs, safety of blood transfusions, respect for personal autonomy, disclosure of information and transplantation procedures. We will discuss issues relating to the use of left over tissue and whether the Human Tissue Act CAP 252, Laws of Kenya, adequately addresses all of these concerns.

In Chapter five we look at the law on informed consent in Kenya and its implications in view of technological advancement in medicine and biomedical research involving human subjects.

Finally, in Chapter six we give our conclusions and recommendations.
CHAPTER I

THE DOCTRINE OF INFORMED CONSENT: AN OVERVIEW

In today’s medical environment a health practitioner, physician or researcher would never consider performing a surgical or diagnostic procedure on a patient or put an individual in a clinical trial, without first obtaining informed consent from the patient. This is not only important from a risk management point of view but is also a basic requirement of the proper practice of medicine.

This chapter will therefore discuss the history of the doctrine of informed consent. But before we undertake to trace the history, it is necessary at the outset to establish the boundaries between the practice of medicine and research involving human subjects. This is because most commonly both occur together, for example, human tissue like blood or bone marrow may be drawn for diagnostic examination or small pieces of tissue may be taken by biopsy for pathological examination and diagnosis, and larger amounts of tissue may be removed surgically during an operation for malignant or other disease: Left over tissue that is not discarded or destroyed as clinical waste after use may be made available for scientific research, medical training, scholarship, evaluation and review of medical procedures. All these activities may be performed by one person in which case he or she will be the physician and researcher at the same time or the tissue may be passed on to other researchers. It is therefore important in our view, to distinguish between biomedical research and behavioral research on the one hand, and the practice of therapy on the other, in order to know what activities ought to be taken into account for the
protection of human beings. The distinction will also form the basis for the conceptual framework upon which the doctrine of informed consent is built.

**Boundaries between Medical Practice and Research**

As discussed above, the distinction between research and practice is blurred partly because both activities often occur together (as in research designed to evaluate a therapy), and partly because departures from standard practice are often called "experimental" when the terms "experimental" and "research" are not even defined.

For the most part, the term "practice" in this paper refers to interventions that are designed solely to enhance the well being of an individual patient and those that have a reasonable expectation of success.

Therefore, the purpose of medical or behavioral practice is to provide diagnosis, preventive treatment or therapy to patients. By contrast the term "research" designates an activity designed to test a hypothesis, or permit conclusions to be drawn and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a physician or healthcare professional departs, in a significant way, from a standard or the accepted practice of providing healthcare, then measures must be put in place for the protection of human subjects who may be victims of such departures. Such measures come in the form of "basic ethical principles"
which refers to those general judgements that serve as a basic justification for the many particular ethical prescriptions and evaluations of human action. Of these, three stand out, namely, respect for persons, beneficence and justice. These three ethical principles are relevant to our study of healthcare and the informed consent regime.

1. Respect for persons

This ethical principle requires of us to respect other people. This is because people have capacity to think, reason, use language and live in complex relationships with one another, thereby creating cultures of their own and allows individuals to pursue life within these cultures. This capacity of creating a life of our own is both an essential feature of common humanity and yet marks out each one of us as a unique being who has value and worthy of respect.

If we hold that every person is worthy of respect, then we must commit ourselves to taking their interests into account in our actions. We may not use them as a mere means either to our own ends or to the welfare of others, and, if we agree that they are the best guardians of their own interests, they should be involved in decisions which affect them. Therefore, we should not increase their risk even when they are sick or dead, misinform them or violate the integrity of their beliefs. We should support their sense of self-respect and self-worth, respect the vulnerable and indeed respect their autonomy.

To respect autonomy is to give weight to a person’s considered opinion and choices while refraining from obstructing his/her actions unless such actions are clearly detrimental to others. To show lack of respect for an autonomous person is
to repudiate that persons considered judgements, to deny an individual the freedom to those considered judgements, when there are no compelling reasons to do so.

However, we must appreciate that, not every human being is capable of self-determination. The capacity for self-determination matures during an individual’s life and some individuals may lose their capacity wholly or in part because of illness, mental disability or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

It is against this background that we will discuss the concept of informed consent and its relationship to the principle of respect for persons, or the autonomy of a person.

2. Beneficence

The term “beneficence” is often understood to cover acts of kindness or charity\textsuperscript{27} that go beyond strict obligations. Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence.

In this paper, beneficence will be understood in the stronger sense, namely, that of a higher obligation or a commitment not to do harm and to maximize possible benefits from the activity being carried out for the recipient.

\textsuperscript{27} Reader’s Digest Oxford “Complete Wordfinder” (1\textsuperscript{st} Edition) (Oxford: Clarendon Press, 1993)
The "do not harm" rule is a fundamental rule of medical ethics. It is in fact expressed in the Hippocratic Oath\(^{28}\) and may be extended to the realm of research so that one should not injure another regardless of the benefits that may come to others. However, we must note that in order to avoid harm we require to learn and know what is harmful, and in the process of obtaining this information, persons may be exposed to risk of harm. The Hippocratic Oath also requires physicians to benefit their patients "according to their best judgement". Learning what will in fact benefit may require exposing persons to risk. The problems then that are posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when can benefits be foregone because of the risks, and how does this affect the rights of the patient or the research subject for that matter.

The principle of beneficence often occupies a well defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effecting ways of treating childhood diseases and fostering health, development are benefits that serve to justify research involving children, even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. This seems to portray the principle of beneficence to be an unambiguous one. However, a different ethical problem remains, for example, what about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some argue that such research is

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inadmissible as it is done without their consent while others point out that this limit would rule out much research which promises great benefit to children in the future. Our argument here is that participation in research by such a child is in fact of benefit to the child especially if they are older, in that it is a pro-social and altruistic activity which may help to develop a child’s sense of duty to the community. However, again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict with the doctrine of informed consent and force difficult choices, some of which will be discussed later in this paper.

3. Justice

An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of looking at the principle of justice is that equals ought to be treated equally. However, this statement begs for an explication. Who is equal and who is not? What considerations justify departure from equal distribution? Most writers allow that distinctions based on experience age, deprivation, competence, merit and position constitute criteria justifying differential treatment for certain purposes. It is necessary therefore, to explain in what respects people should be treated equally. There are many accepted formulation of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. For Perelman in De la Justice in 1945\textsuperscript{29} these formulations are: (i) to each person an equal share, (ii) to each person

\textsuperscript{29} Reprinted in C H. Perelman "The idea of Justice and the problem of Argument" (1963), Chapter I
See also J.G. Ridall "Jurisprudence" (2\textsuperscript{nd} Edition), (Derbyshire: Butterworths, 1999). 199-203

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according to individual need, (iii) to each person according to individual effort, and (iv) to each person according to societal contribution and to each person according to merit.

Issues of justice have long also been associated with social practices such as punishment, taxation and political representation. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private wealthy patients. This is exemplified by the exploitation of unwilling prisoners as research subject in Nazi Concentration Camps which has been condemned as a particularly flagrant injustice.

In the United States of America, in the 1940's, the Tuskegee Syphilis study used disadvantaged, rural black men to study the untreated course of a disease that was by no means confined to that black population. These subjects were even deprived of demonstrably effective treatment in order not interrupt the project, long after such treatment became generally available to all others against their will. We can see the great injustice. These black people were chosen because of their race.

It is against this background that conceptions of justice are relevant to the doctrine of informed consent and more specifically in research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (for example, particular racial and ethnic minorities, rural or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied.

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Justice demands that the selection of research subjects be non-discriminatory, results of research should provide advantages to all and that research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the results of research.

It is important for us to understand the above three ethical principles namely, respect for persons (autonomy), beneficence and justice as they will help us understand origins and importance of informed consent which we now turn to.

The History of Informed Consent

It is necessary for us to have an overview of the milestones that have been made in the ever developing field of medical ethics and consent. This will show how the concept of obtaining consent for medical treatment or research has developed over the years and will provide us with the rationale for current practice that requires physicians and researchers to obtain consent before treating patients and before participants participate in clinical trials.

The concept of consent to treatment is a relatively new phenomenon. In ancient times during the Greek, Romans and Egyptian civilization there was no such thing as a patient’s informed consent to medical treatment. However, as social trends changed, and as people became more focused on human rights, the concept of consent became the subject of case law mainly in the United States of America and the United Kingdom. The resultant jurisprudence has been translocated to other parts of the world as common law and used widely as judicial precedents.

30 Singapore Medical Journal (February 1992), 33
The concept of consent to treatment can therefore be said to be located in social trends, developments in technology, the demise of paternalism and the development of case law on consent. We shall discuss briefly these locations below.

1. Social Trends

Just like other changes in social habits, informed consent is the societal response to the demystification of medicine. The practice of medicine for a long time was paternalistic, and the physician was a know all and lorded it over his patients. This is no longer the case and the practice of medicine is no longer paternalistic.

The fundamental principle underlying the concepts of medical ethics is that of the autonomy of the patient. This means that the patient has the right to decide his or her own medical destiny; the physician may advice, but the patient decides. It is unacceptable for one individual including the physician and relatives to attempt to exert unconstrained power over the fate of another individual. The right of self-determination and autonomy is a fundamental principle of International Human Rights Laws as set out in various international conventions particularly Articles 1 and 5 of 1948 United Nations Declaration of Human Rights, Articles 1 and 7 of the 1966 International Convention of Civil and Political Rights and Articles 4, 5 and 9 of the 1958 African Charter on Human and Peoples Rights all of which Kenya is a signatory.

31 Paternalism here means what a group of physicians decide themselves to do in a given circumstance without giving the patient the options.
In Kenya the right of self determination and body integrity is guaranteed under sections 70, 74, 82 and 84 of the Constitution and Sections 250 and 251 of the Penal Code CAP 63 Laws of Kenya.

The lay public, therefore, in recognition of the right to self-determination is demanding for enough information from medical practitioners and or clinical researchers. What they are saying is that, given enough information, they will rationally make their own medical decisions and this has led to the development of the concept of informed consent.

The concept of respect for the person (autonomy) pervades the whole of medical practice. It pre-supposes that there is rational and honest communication between doctors and patients. It pre-supposes the possibility of dialogue. However, we know that this is not available to say, the fetus, the neonate or the mentally challenged. Moreover, autonomy cannot be absolute, it is modified by financial considerations, availability of resources, by relationships with others than patients – for example, the patient’s family and not least by the autonomy of the physician. There are also circumstances in which the physician must choose which set of interests is to prevail – say in abortion cases. We will try to suggest answers to some of these concerns later in this paper.

2. The Rise of Technological Medicine

The development of technology and technology based medicine has also contributed to the development of the concept of informed consent. The interval between the advent of scientific medicine in the late 1890’s and the rise of technological medicine in the 1950’s was a period with relatively few effective treatments. The patient’s choices were usually limited to one treatment or no treatment at all. More importantly fewer conditions had been diagnosed and
medicalised. Symptomatic disease rather than laboratory values drove patients to seek treatment.

In this kind of situation it was reasonable for patients to expect physicians to make all the necessary medical decisions for them. This was an extension of the traditional paternalistic physician-patient relationship. The decision or treatment was based mostly on technical medical considerations. However, with the development of technological medicine, patients realized that there might be more than one way to treat their conditions.

With the realization of the luxury of several effective treatments, came the demand for more information about therapies that were available to enable a patient make a choice. This again led to the development of the concept of informed consent. The growth of technology therefore determined the direction and transformation of the concept of informed consent.

3. The Demise of Paternalism

Traditional medical paternalism was based on the importance of faith in the absence of effective treatments. Physicians occupied a quasi-religious role, providing solace rather than salvation. With the development of more technology based invasive medical procedures, more finely tuned but highly toxic drugs, and more diseases that are defined by a medical or laboratory finding rather than by a patient's symptoms, the importance of the paternalistic role began to deteriorate. Choosing treatments is no longer the simple exercise of diagnosing the patient's condition and having that diagnosis determine therapy. A diagnosis now may trigger a universe of possible therapies. The selection of a treatment from this universe becomes a value judgement based on the relative risks and benefits of the
Physicians may be experts in determining the medical risks of a treatment, but it is only the patient who can determine the relative acceptability of these risks and therefore, the need for his consent. For example, some patients will risk substantial disability on a chance of a complete cure of chronic pain. For others, chronic but bearable pain is preferable to the chance of disability secondary to treatment. This weighing of risks is idiosyncratic to the patient's individual risk taking behavior and cannot be predicted by a physician. In the paternalistic model, physicians assumed the tasks of making this risk benefit decisions for the patients. Problems arose as patients began to question the consequence of these decisions. Once patients realized that there might be more than one way to treat their conditions, they began to question the physician's authority to make unilateral treatment decisions and this led to the development of the concept of informed consent.

4. The Development of Case Law on Consent

Patients expressed their dissatisfaction with paternalism through lawsuits. In a small number of cases in the 1960's and early 1970's physicians began to be sued for obtaining consent without informing patients of the risks of the proposed treatments. In almost every one of these cases, failure to inform the patient properly was only one facet of substandard care. A few courts held that a patient

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32 Richards E.P, III and Rathburn K.C. "Medical Care Law" (1st Edition), (Gaithersburg, Maryland: Aspen Publishers, 1999) 209
33 Cobb-v-Grant 104 Cal Rpt2 505 1972 and Schweitzer-v-Central Hospital (1974) 53 DLR (3d) 494

29
was entitled to be informed of the risks of treatment as part of the consent process. These opinions were seized upon by legal scholars, who then fashioned the theory of informed consent to medical care.

As more courts began to recognize a patient’s legal right to be informed about the risks of treatment, this was transformed into an individual liberties issue. Physicians who did not inform patients adequately have been accused of oppressing their patients and violating their human rights.

This has made physicians feel that their integrity is being challenged and has led to the current animosity between physicians and legal scholars. The physicians argue that all that they are doing is in good faith and they are attempting to shield patients from unpleasant medical information.

The courts on their part, despite much language about the special relationship between physicians and patients, have inexorably moved to the position that physicians who assume the right to make decisions for their patients also assume the consequences of those decisions. We shall discuss this issue further when we discuss the case of Bolam –V- Triern Hospital Management Committee.

Consent for medical care is a patient’s agreement for treatment and or any other diagnosis. Proper informed consent requires that a patient be informed about a particular treatment, alternative treatments, and their potential risks and benefits. The patient should understand the information provided by the physician and the patient freely and knowingly gives consent. The consent should be documented preferably and where possible with a signed form.

35 Hopp-v-Lepp (1979) 98 DLR (3d) 464
36 Bolam-v-Triern Hospital Management Committee (1957) 2 ALL ER 118, (1957) 1 WLR 582
In the often-quoted words of Mr. Justice Cardozo in the United States case of *Schloendorff v. Society of New York Hospital*,37 “Every human being of adult years and sound mind has a right to determine what shall be done with his own body...”. This case saw the beginning of the development in the United States of the doctrine of informed consent. Its central tenets have been accepted by courts in the United Kingdom and indeed the rest of the world. Thus British courts would undoubtedly endorse the words of the court in *Union Pacific R. Co v Botsford*38 where it was said that:

> No right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.39

The development of rules which require patients to agree in meaningful terms to recommended treatment is designed to achieve a number of goals. First and most importantly, these rules are intended to secure the right of the individual to act in an autonomous or self-determining manner.40 Lord Donaldson has said:

> The ability of the ordinary adult to exercise a free choice in deciding whether to accept or refuse medical treatment and to choose between treatments is not to be dismissed as desirable but is essential. It is a crucial factor in relation to all medical treatment.41

Secondly, the rules are intended to impose on physician’s researchers an obligation to make appropriate disclosure of relevant information to the individual, in order that the exercise of autonomy is meaningful. Thirdly, they provide a

37 Schloendorff v. Society of New York Hospital 105 NE 92 (NY 1914)
38 Union Pacific R. Co v Botsford 141 US 250 (1891)
39 Ibid at Page 251. This statement was approved in the US Supreme Court in the case of *Cruzan v. Director, Mo Dept. of Health* (1990) 497 US 261 at 269
41 In *Re F (Mental Patient: Sterilization)* (1990) 2AC1
measure of protection for physicians or researchers by rendering lawful what could be otherwise amount to a civil assault/battery or trespass to the person.\textsuperscript{42}

These three requirements are all interlinked and establish that any touching without consent amounts \textit{prima facie} to an assault. The central issue therefore is about self-determination, the right of the individual to make a real choice, rather than about the provision of consent, particularly since consent is merely one of the options which a patient has. He or she may well receive information and choose an alternative therapy or refuse treatment altogether subject to certain limitations. This choice need not be rational and the reasons for making it may not be known.\textsuperscript{43} What is important is that the individual is given an opportunity to make a decision. The issues at stake are the quality of the information which is provided and its ability to permit self-determining decisions, not the content of the outcome.

It can therefore be concluded that patient autonomy is only protected where there is a meaningful choice made by the patient, on the basis of adequate information.

The importance of the process by which consent is given or withheld was reaffirmed in the Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine.\textsuperscript{44}

In Article 5, the Convention states as follows: -

\begin{quote}
An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the
\end{quote}

\textsuperscript{42} Collins-v-Wilcock (1984) 1 W.R.L. 1172 see also F-V-West Berkshire Health Authority (1989) 2 All ER 545

\textsuperscript{43} Sidaway-v-Board of Governors of Bethlem Royal Hospital and the Maudsley Hospital (1985) AC 871 at P,914

\textsuperscript{44} European Treaty Series/164,4.IV.1997

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intervention as well as on its consequences and risks. The person concerned may freely withdraw Consent at any time.

Furthermore, the Convention mandates that subject to specified exceptions an intervention may only be carried out on a person who does not have the capacity to consent for his or her direct benefit."  

The doctrine of informed consent is clearly part of United States jurisprudence and its central tenets have been accepted in courts all over the world notably in the United Kingdom as we have seen. It has also found its way into Kenya as common law.

In Kenya the doctrine of informed consent has found its way into our jurisdiction courtesy of English law When Kenya was colonized by the British they came with their laws. This is reflected under Section 3(1) of the Judicature Act which recognizes common law, equity together with the English statutes of general application as sources of Kenya law subject to the proviso.

"But the common law, doctrines of equity and statutes of general application shall apply so far as the circumstances of Kenya and its inhabitants permit..."  

Therefore Kenyan courts when faced with an action involving consent for medical care have to look at the English common law for guidance. However they have to take into account local circumstances.

The local "circumstances" is hardly surprising in a country of diverse tribes and backgrounds, practicing, and having a variety of values, customs and religions. Importing the rules of English law in its entirety would mean the imposition of a totally alien system on a society quite different from the English society. Kenyan

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45 Article 6.1
46 Judicature Act CAP 8 Laws of Kenya
47 Ibid: Section 3(1)(c)
courts are therefore at liberty either to reject or modify any rule of English common law or equity. This should be the case in consent law. However, there is not much evidence in this direction. Generally the courts in Kenya follow the rules of English law without taking into account local circumstances.

Lastly but not least, we locate the notion of consent in the old adage: *Volenti non fit injuria* – no wrong is done to one who is willing. The basic considerations are common in all jurisdictions and indeed in all domains of life: If you take my car, and I lent it or gave it to you, then I am willing, so I am not injured, by your driving off. On the other hand, if I neither lent nor gave it, indeed I am unwilling, then I am wronged when you drive off in my car. This ancient principle is of great value in medical ethics and is constantly invoked. If a surgeon operates on a willing patient, then the operation is legitimate and the patient is not wronged/even if things turn out badly: If a surgeon operates on an unwilling and unconsenting patient then the patient is wronged (even if no physical harm is done). In general, action that is clearly guided by a therapeutic intention must also be consented to by the particular patient or volunteer if it is to be ethically permissible.

So far for the history of informed consent, we shall now discuss the disclosure standards for informed consent.

**DISCLOSURE STANDARDS FOR INFORMED CONSENT**

The core of the controversy over informed consent is the choice of a standard by which informed consent is judged. Physicians argue, correctly so, that they have always talked to patients about proposed treatments. It is not talking to patients
that they object to; it is the laws intrusion into what is said. Many jurisdictions
notably in the United States and United Kingdom have sought to minimize the
intrusion by adopting disclosure standards based on physician expectations. These
are;

- The community standard (professional or intellectual community)\(^48\)
- The reasonable person or patient standard
- The therapeutic privilege

1. **The Community Standard**

The community standard is the older standard and is paternalistic and reflects
the traditional defense of the law towards physicians. It is based on what physicians
as a group does in a given circumstance. It requires that the patient be told what
other physicians in the same community would tell a patient in the same or similar
circumstances. “Community” here refers both to the geographical community and to
the specialty (intellectual or professional community) of the physician. It is
commonly referred to as the *Bolam* principle.\(^49\)

The community standard usually requires that the patient be told little about
the risks of the treatment or possible alternatives. In the extreme case therefore
the community standard can shelter, telling the patient nothing other than the name
of the proposed treatment and a brief description of it. In this extreme situation,
physicians choose not to inform patients about the risks of the treatment.

\(^{48}\) See Infra: No. 55 Bolam-v-Triern Hospital Management Committee (1957) 2 All ER 118
The community standard can have extreme results in limited subspecialty areas of practice. In these areas, the number of physicians is small and is characterized by few hospitals. The result is an intellectually homogeneous group of physicians who tend to approach patient care in a similar manner: Here the subspecialty practitioners or in our case the clinical officers become true believers in the efficacy of a given treatment and promote that treatment to patients. In the situation, the community standard will be to offer the patient only enough information to convince him or her to have the treatment. Risks will be ignored because the physicians have convinced themselves that it would be unreasonable to refuse the treatment.

Another area in which the community standard becomes a problem is when a small group of a larger specialty adopts a therapy that is rejected by the majority of the specialty. Since informing their patients of the majority view would make it impossible for them to perform the procedure, the minority view physicians ignore the controversy and proceed with the treatment. For example in the United States there has been a great controversy in Ophthalmology over performing radial keratotomies, which is an incision into the cornea of the eye. A small group of ophthalmologists began performing this procedure on a large number of patients without the traditional controlled studies on the benefits and long-term risks of the procedure.\(^5^0\)

A disclosure based on the views of the majority would have required that the patient be told that this was an unproved, experimental treatment that carried

\(^{50}\) Freifeld K. "Myopic Haste" (100,000 plus have had new eye surgery) Forbes Magazine, 6th May 1985, 135
potentially severe long-term risks. Very few patients would consent to an essentially
cosmetic procedure given this information. As a result the majority view was
discounted, and patients were told little about the uncertainty. When a national
study panel disputed this practice and called for proper studies of the procedure the
advocates of radial keratotomies sued the members of the study panel for antitrust
violation. The court found these allegations groundless and ruled for the study
panel members.

From a physician’s perspective, the community standard provides little
guidance in deciding what to tell patients. Physicians do not routinely discuss what
they tell patients, medical journals do not publish articles on the proper disclosure
for specific circumstances or treatments, professional societies do not promulgate
standards for disclosure because they fear antitrust or anticompetition litigation by
physicians who offer unorthodox treatments. A physician who wants to comply with
the community standard has a difficult task in establishing what disclosures the
standard would mandate for a given treatment in particular situation. For example
what disclosure will be required of a physician working in the rural areas as opposed
to one working in an urban area?

This uncertainty arises because the community standard is not rooted in
medical practice. It will appear to be rooted in law, where it is used to determine
whether a specific patient was given enough information. It is therefore a defensive
standard.

51 Norman C. “Clinical trial stirs legal battles”. Legal disputes in Atlanta and Chicago over surgery for
Myopia raise issues or how controversial surgical techniques should be assessed. Science 1985: 1316.227
52 Schachor-v-American Academy of Ophthalmology, Inc. 870 F.2d 397 (7th Cir.1989).
2. **Reasonable Person/Patient Standard**

The reasonable person/patient standard requires that a patient be told all of the material risks that would influence a reasonable person in determining whether to consent to the treatment.\(^{53}\) Although hardly less ambiguous than the community standard, the reasonable person standard has the advantage of encouraging physicians to discuss the proposed treatment with the patient more fully.

Most jurisdictions notably in the United States and the United Kingdom are abandoning the paternalistic community standard in favour of the more patient oriented reasonable person/patient standard. This is because a standard based on reasonableness, means that courts will use common sense to determine what should have been done. In jurisdictions like in the United States where jurors decide cases, in an informed consent case, the jurors will decide what they would have wanted to be told about the proposed treatment if they were the patients.\(^{54}\) This weighs the standard towards disclosure, since each juror is more likely to add to the list of necessary information than to argue that another’s concerns are unreasonable.

However, it will appear that in the United Kingdom they are as yet to accept fully the reasonable patient standard. The requirements of the legal duty to inform patients have been significantly developed in case law during the last decade in the United Kingdom. In 1985 for example, the House of Lords decided in the *Sidaway*\(^{55}\) case that the legal standard to be used when deciding whether adequate information had been given to a patient should be the same as that used when

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\(^{55}\) *Sidaway v. Board of Governors of Bethlem Royal Hospital* (1985) AC 871
judging whether a doctor had been negligent in their treatment or care of a patient, a doctor would not be considered negligent if their practice conformed to that of a responsible body of a medical opinion held by practitioners skilled in the field in question (known as the “Bolam test”)\textsuperscript{56}

\textit{Bolam} concerned the administration of electro-convulsive therapy without an anaesthetic as was common at the time-to a mentally ill patient to whom the risk of facture in such a procedure had not been explained. The court expressed the view that the doctor was entitled to proceed without explanation of the risks in the light of the patient’s condition. As the judge said in his charge to the jury:

You may 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 cannot be criticized if he does not stress the dangers, which he believed to be minimal, which are involved in their treatment…\textsuperscript{57}

This sympathetic attitude to the professional privilege or community standard found support in the influential case of \textit{Smith-v-Auckland Hospital Board}.\textsuperscript{58} Here the patient alleged that he did not give his informed consent to the performance of an aortogram and was not told of the risks involved. In a dictum which has widely been referred to in the British courts, Woodhouse J. outlined what should be taken into account in deciding what a patient should be told.

As it seems to me, 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

\textsuperscript{56} \textit{Bolam-v-Friern Hospital Management Committee} (1957) 2 All ER 118
\textsuperscript{57} Ibid: Per McNair J (1957) 2 All ER 118 at 124
\textsuperscript{58} \textit{Smith-v-Auckland Hospital Board} (1964) NZLR 241 SC, revsd (1965) NZLR 191 NZCA
that patients should be treated as intelligent, rational people to whom matters should be explained in some detail.⁶²

The reasonable person/patient standard therefore increases the amount of information that the patient must be given and changes the substance of that information whereas the community standard is concerned with the old question of treatment versus no treatment. The reasonable person/patient standard is concerned with the modern problem of choosing among alternative treatments. To make an informed choice, the patient must be told about the risks and benefits of all the acceptable treatments and the consequences of no treatment. This becomes a sensitive issue because specialty practice lines are often based on a particular approach to treatment. Surgeons do not like discussing the medical management of their patients, and family practitioners are reticent to recommend highly technical procedures for conditions that may be managed more conservatively.

The disclosure of alternative treatments is crucial when the physician is being pressurized by a third party payer say a health management organization or an employer to steer the patient to a less expensive treatment. The patient must be informed of alternative treatments and their relative benefits. If the physician believes that an alternative treatment is preferable to the treatment that the third party payer is advocating the patient must be told of this conflict. The physician must never imply that a financially motivated treatment decision is medically preferable. Financial considerations must be explicitly discussed, or the physician commits a fraud on the physician – patient relationship.

In considering therefore what information to provide, the physician should try to ensure that the patient is able to make a balanced judgement on whether to give or withhold consent. As we have seen, case law on this issue is legion and evolving. It is therefore advisable to inform the patient of any material or significant risks in the proposed treatment, any alternatives to it and the risks incurred by doing nothing. A British Court of Appeal judgement stated that it would normally be the responsibility of the doctor to inform the patient of “a significant risk, which would affect the judgement of a reasonable patient.”

It is also important that doctors go a step further and do their best to find out about a patient’s individual needs and priorities when providing information about treatment options and if the patient asks specific questions about a procedure or therapy and its associated risks, these should be answered truthfully.

In the rare event that the physician believes that to inform the patient about the risks of a particular procedure would have a deleterious effect on the patient’s health then she should state this view, and the reasons for it should be recorded in a patient’s notes. It is important to note that the mere fact that the patient might become upset by hearing the information or might refuse treatment is not sufficient to act as a justification.

Some patients may also wish to know very little about the treatment, which is being proposed. If information is offered and declined, it is always good practice for the physician to record this fact in the notes.

The most significant difference between the community standard and the reasonable patient standard is the presentation of the physician’s personal recommendations. The community standard rests on the inherent coercion of forcing the patient to choose between treatment and no treatment, between continued care by the physician and loss of care. Whereas the reasonable patient standard, with its emphasis on alternatives, allows the patient to reject a given treatment without rejecting the physician. The change in emphasis, we must say, reflects the reality of contemporary medical practice. In a competitive market place, physicians need patients as much as patients need physicians. A win-win situation. This recognition of mutual dependence is beneficial unless it results in physicians advocating trendy treatments to gain a marketing edge in which case they can be accused of violating antitrust laws.

Both the community standard and the reasonable patient standard are used for judging the information to be given to passive patients who do not ask questions. However if the patient asks questions, the physician must answer the questions truthfully. More importantly the answers must be sufficiently complete to convey the required information adequately. The physician cannot hide behind the patient’s inability to phrase a technical question properly. Under either standard, a patient who asks to be told all the risks of a procedure is entitled to more information than a patient who sits mute. Failure to disclose a risk in reply to a direct question may constitute fraud, even if the appropriate standard for judging informed consent would not require that the risk be disclosed.
Therefore, the reasonable patient standard approach most fully satisfies the requirements of self-determination but can be criticized on the grounds that it leaves little scope for the exercise of clinical judgment by the doctor. What is the point in burdening a patient with knowledge of risks when the doctor knows or suspects that such information will only serve to retard recovery? It may be more important to reassure the patient as an important and essential part of the treatment, rather than dwelling or even mentioning the risks, which may as well harm the patients or aggravate their conditions.

Although it might be ethically desirable for patients to be fully informed as possible, the time spent in explaining the intricacies of procedures could be considerable, particularly if the doctor is expected to deal with very remote risks. Doctors are very busy people (this is the case in rural areas where you may only have one doctor in a hospital) and do not have the time to spend on unduly lengthy explanations of all the ramifications of treatment.

A compromise must be to place on the doctor the duty to inform the risks of a therapy only in so far as the risks are material, provided there is no clinical reason to keep such information away from the patient.

3. The Therapeutic Privilege

The therapeutic privilege is an exception to the need for informed consent, rather than for any consent. It ostensibly allows the physician to withhold information from a patient if that information would psychologically harm the patient and thus imperil the patient's physical health. The therapeutic exception was first
broached in Hawaii in one of the early informed consent cases, *Nishi-V-Hartwell* which was decided in 1970.

*Nishi* involved consent to angiography for an elderly dentist. He was not told of the risks involved and was paralyzed as a result of the test. The defendants claimed that they did not tell him the risks because it was not the standard of care to disclose those risks, and because they were concerned he would be frightened and would refuse the treatment.

At the time the case was decided, Hawaii used the community standard for informed consent, which required plaintiffs to have expert testimony as to what the reasonable physician would have told the patient. The plaintiff had no expert, so the court dismissed the case. In doing so, however, it also discussed the duty of a physician to do whatever is best for the patient.

Thus the therapeutic exception to the need for informed consent arises from the discredited view that information about risks of treatment or the existence of diseases such as cancer should be withheld from patients to foster the proper mental attitude for recovery. Most court decisions notably in *Bolam, Sideway,* and legal articles dealing with informed consent take care to acknowledge that there may be circumstances when it is in the patient’s best interest not to be informed of the risks of the proposed treatment.

Although courts in most jurisdictions constantly reaffirm the existence of the therapeutic exception, they uniformly reject it as a defense in specific cases. For example even in Hawaii, where courts specifically overruled *Nishi* and adopted the

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64 *Nishi-v-Hartwell*, 473 p.2d 116 (Haw.1970)

65 Imaging of blood vessels
reasonable patient standard for informed consent still say that the physician can
defend with testimony that a reasonable physician would have withheld the
information.\textsuperscript{66}

The choice between the ‘reasonable patient standard’ and the ‘therapeutic
standard’ is a difficult one. Whatever stand one takes, a decision of some court can
be found to endorse one’s preferred approach. In the United States for example,
there are some jurisdictions in which the full disclosure rule applies and others in
which the therapeutic standard is accepted. Within the Commonwealth, there are
decisions ranging from the endorsement of the deliberate medical lie to the
acceptance of the extreme patient – oriented approach which required full disclosure
of risk.\textsuperscript{67} The diversity of opinion on this matter in academic circles is equally
diverse. Some argue for full disclosure as this satisfies the requirements of self-
determination and choice whereas some academicians urge caution in the face of
what is seen as an indirect and inappropriate means of widening the potential
liability of doctors which may lead to distrust and an increase in the practice of
legalistic and defensive medicine.

In our view a compromise would be to place on the physician the duty, to get
a court appointed guardian to make medical decisions or consult relatives where the
physician really believes that it would do significant harm to a patient were she to
be informed of the risks of a proposed treatment. Then it would be appropriate to
consider petitioning the court for the appointment of a guardian.

\textsuperscript{66} Carr-v-Strode, 904 p.2d 489 (Haw 1995)
CHAPTER II
OBTAINING INFORMED CONSENT

The doctrine of informed consent is a special case of the broader notion of assumption of risk – *Volenti non fit injuria*. Whenever a person knowingly engages in a risky activity, that person consents to the risks of the activity.

In order for a patient to give valid consent, a patient needs to understand in broad terms the nature and purpose of the procedure or therapy that he is about to undergo. Therefore in the process of discussing the risks, benefits and potential alternatives to a given treatment, the physician and the patient have an opportunity to ensure that there are no misunderstandings about the patient’s complaint and the proposed treatment. Any misrepresentation of these elements will invalidate consent. If the patient is going to be treated under anaesthesia then information about anaesthesia should be given as well as information about the procedure itself.

Therefore, for consent to be effective the person being treated or being used as a research subject must know the risks that are being assumed, assume these risks voluntarily and it must not be against public policy to assume the risks. Let us now discuss some of these requirements in some detail.

1. Known Risks

People can assume risks that they know about. For most commonplace activities, such as fishing or riding a bicycle, the risks are well known and are implicitly assumed by engaging in the activity. It is also possible to engage implicitly in the risks of medical care. For example, a physician undergoing general
anaesthesia would be assumed to know that general anaesthesia carries a risk of anoxic\textsuperscript{68} brain damage. He or she would implicitly assume this risk without the need for an explicit informed consent.

However, most patients do not have the necessary background medical knowledge to assume specific risks of treatment implicitly. Prior to the advent of informed consent, the patient was assumed to know that medical treatment was risky. It was assumed that since the person sought treatment knowing that it was risky, he or she was assumed to have accepted that the risk of treatment was less than the risk of the medical condition. In such a situation it can be concluded that the law was not concerned with the particular form that a risk might take.

However, advances in medical technology seem to have changed all that and have caused a proliferation of choices in medical therapy. Patients are no longer limited to the choice between treatment or no treatment. With many possible therapies for a given condition, courts are likely to reject the implicit assumption of risk. A patient must now be told of the risks that he or she is assuming. The more particularized the information is about the potential adverse consequences of a treatment the more effective is the assumption of risk.

Case law on this issue is evolving. It is therefore necessary that a physician inform the patient of any material or significant risks in the proposed treatment, any alternatives to it, and the risks that can be incurred if nothing is done. This has found judicial support in \textit{Pearce} where the court stated that it is normally the

\textsuperscript{68} From the noun 'anoxia' a condition in which the tissue of the brain receives inadequate amounts of oxygen causing it damage – Oxford Concise Medical Dictionary – 6\textsuperscript{th} Edition (Oxford University Press)
responsibility of the doctor to inform a patient of 'a significant risk 'which would affect the judgement of a reasonable patient.\(^{69}\)

2. Unknown Risks

Medicine is not a perfect science. All medical care is associated with known and many times unknown risks. The physician must tell the patient of the known risks of the therapy or procedure, but this is not a guarantee that other problems cannot occur, patients may assume these unknown risks if three conditions are met namely:\(^{70}\)

- The risk is unknown (or of such a low probability that it is not known to be casually related to the therapy)
- The patient should be informed that the risks disclosed are not the only ones
- The medical rationale for the treatment or procedure is sound.

The requirement that the medical rationale for the treatment or procedure be sound means that a patient cannot assume the risks of a negligently recommended treatment. A patient who suffers a complication from an improper treatment must always sue the physician who recommended the treatment. A detailed consent form, listing all the risks of a treatment, is no protection if the treatment is unnecessary. We do see many of these unnecessary procedures in Kenya where patient kiting is rampant. If a patient can prove that a treatment was unnecessary then the consent to risks of the treatment becomes ineffective.

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\(^{69}\) Pearce v United Bristol Healthcare NHS Trust (1999) 48 BMLR 118

\(^{70}\) Richards III E.P. and Rathbun K.C. in "Medical Care Law" (1st Edition) (Gaithersburg, Maryland: Aspen Publishers, 1999), 214
3. Voluntariness

Consent to medical care can be truly voluntary only when it is reasonable to reject the care. To be valid, consent must be given voluntarily and freely, without pressure or undue influence being exerted on the patient either to accept or refuse treatment. Such pressure can come from colleagues, partners, family members, third party payers as well as healthcare professionals. Physicians should be aware of this possibility and where appropriate should arrange to see the patient on their own to establish that the decision is truly that of the patient.

Of course this can only be possible where you have a reasonable patient who is able to understand the risks of the procedure. Where the patient does not understand the intricacies of the procedure and or is illiterate or has no capacity then some other means has to be used to get consent, say, from a guardian or parent. However, any decision made must be in the best interest of the patient.

When patients are seen and treated in environments where involuntary detention may be an issue, such as prisons and mental hospitals, or in our case prisoners are taken to Kenyatta National Hospital or any government hospital and chained to their hospital bed, there is a potential for treatment offers to be perceived coercively, whether or not this is the case. Coercion invalidates consent and care must be taken to ensure that the patient makes a decision freely. Coercion should be distinguished from providing the patient with appropriate reassurance concerning their treatment or pointing out the potential benefits of treatment for the patient's health. However, any threats such as withdrawal of any privileges or loss
of remission of sentence for refusing consent, or using such matters to induce consent are not acceptable.

We have to appreciate that consent becomes a legal issue if the physician coerces the patient into accepting a treatment for which there are acceptable alternatives. This coercion may be explicit, like telling the patient that they will die if the proposed procedure is not carried out or implicit as when the physician ignores to discuss alternatives or simply makes a financial intimidation. Physicians who cooperate with third party payers to limit a patient’s treatment options undermine the voluntariness of patient consent. Examples of third party payers in Kenya include medical schemes that are arranged by employers on behalf of their employees. Most of these schemes limit the employee’s treatment options and therefore violate the voluntaries of patient consent. In fact most of these schemes even dictate that generic drugs be prescribed and not patented drugs. They go as far as dictating which clinics employees should go and which doctor to be seen. Most of the clinics that these doctors recommend do not have the facilities to provide good healthcare and the patient’s best interests are compromised. This is clearly a violation of the employee’s rights of choice. However the employers and the healthcare providers escape justice because there is no specific healthcare consent law in Kenya.

4. Public Policy

A patient may assume only risks that arise from appropriate care. For example, any operation done under general anaesthesia carries a small risk of
anoxic brain damage. Assume that a patient consents to general anaesthesia, including acknowledging the risk of brain damage. The anaesthesiologist then negligently overdoes the patient with an anaesthetic agent, fails to monitor the patient, and discovers the mistake only after the patient is brain injured. In this case the patient’s informed consent to the risks of anaesthesia would not prevent the patient from suing for the negligent administration of anaesthesia.

Here we are reminded of Wahome Mutahi one of the most beloved humourist that Kenya has produced. He was also popularly known as Whispers after the name of the column he wrote for the Daily Nation Newspapers from 1982 – 2003.

In 2003 Mutahi underwent what was supposed to be a routine, minor and painless operation at the Thika District Hospital to remove a lipoma\textsuperscript{71} from his back. He had been assured by a surgeon friend, who had offered to do the operation, that the procedure would take less than fifteen minutes. Possibly because of a blunder by the anaesthetist, he went into a coma from which he never woke up. Mutahi died on 22\textsuperscript{nd} July 2003 at the Kenyatta National Hospital after 137 days in a coma\textsuperscript{72}.

Whether he died from an overdose of the anaesthetic agent or from the administration of the anaesthetic agent into his spinal cord by mistake we shall never know.\textsuperscript{73} However, we do know for a fact that if there is an overdose of the anaesthetic agent or the anaesthetic agent is introduced into the spinal cord then it can lead to a coma and eventual death. What concerns us here is whether the physician discussed the risks, benefits of the procedure, and also the risks that the

\textsuperscript{71} A lipoma is a common brain tumour composed of well-differentiated fat cells – Oxford Concise Medical Dictionary (6\textsuperscript{th} Edition) (Oxford University Press, 2002)

\textsuperscript{72} http://en. Wikipedia.org/wiki/Wahome Mutahi

\textsuperscript{73} Our effort to get the findings of the Medical Practitioners and Dentists’ Board of Kenya which was investigating this matter was futile. (A case of mistrust between the legal profession and the medical profession?)
patient would undergo if he chose not to have the lipoma removed since it was not malignant. If this was not done then the physician did not obtain genuine consent and he can be liable for malpractice.

As a matter of public policy, the law does not allow a medical care provider to force a patient or any other person to assume the risks of negligent medical care because of the involuntary nature of medical care. Medical care is a necessary service and any person providing the service has a duty, so we think, to provide the service in a proper manner. This is intended to preserve the quality of medical care.

5. Medically unnecessary procedures

Medical technology and advancement has proliferated a number of problems for the doctrine of informed consent. The most difficult informed consent problems are those that arise from competently performed but medically unnecessary procedures. The extreme cases are those that involve vanity procedures, such as facelifts and breast enhancements. These procedures pose an informed consent dilemma. Should the patient be allowed to assume all the risks or should the physician assume the risk of negligent treatment. Opinion is divided on this issue. Some think that as medically unnecessary procedures, they may be rejected, and from this perspective, a physician should be allowed to require a patient to assume all the risks of a vanity procedure, including the risks of negligent treatment.

Another perspective, a more moralistic one is that it is improper for physicians to use their skills and position of respect to perform purely commercial treatments. This view looks at the vanity surgery patient as a victim who should not
bear the risks of the physician’s greed. This would lead to the rejection of assumption of risk for all risks, leaving vanity surgeons as guarantors of good results. We agree with this view especially so if there is evidence of overreaching (such as aggressive advertising that implies that the risks are minimal and the benefits fantastic). Such physicians should be held responsible should the vanity surgery not give the desired results.

We now wish to examine the other interests that affect informed consent and the capacity of a patient or research subject to give consent.

CONFLICTS OF INTEREST AND INFORMED CONSENT

When obtaining informed consent the physician or healthcare provider is expected to present an unbiased view of the proposed treatment, presenting the risks as well as the benefits. Although this is important, the most important decision is which treatment to recommend. Is it modern medicine, traditional medicine or do you recommend a collaboration of the two systems where they exist. Even within one system there could be two or more alternative treatments.

If the healthcare professionals’ impartiality in the selection of treatments is compromised, then providing the patient with information about the compromised choice is meaningless. Notorious examples are financial conflict, treating family members, ownership of hospitals and laboratories.

1. Financial Conflicts of Interest

This problem is most extreme in the managed care plans and the so-called medical schemes provided by employers to staff. The managed care plans request
the physicians not to inform the patient about alternative treatments or tests. They provide financial incentives, especially where the physician is employed by employers who encourage physicians to deny patients necessary care. This issue was the subject of the celebrated United States of America case of *Shea-v-Esensten*.\(^{74}\) *Shea* involved a secret incentive medical plan and a patient who was denied even marginally competent care. The court’s summary of Mr. Shea’s medical care is poignant:

After being hospitalized for severe chest pains during an overseas business trip, Patrick Shea made several visits to his long time family doctor. During these visits, Mr. Shea discussed his extensive family history of heart disease, and indicated he was suffering from chest pains, shortness of breath, muscle tingling and dizziness. Despite all the warning signs, Mr. Shea’s doctor said a reference to a cardiologist was unnecessary. When Mr. Shea’s symptoms did not improve, he offered to pay for the cardiologist himself. At that point, Mr. Shea’s doctor persuaded Mr. Shea, who was then forty years old, that he was too young and did not have enough symptoms to justify a visit to a cardiologist. A few months later, Mr. Shea died of a heart attack.

In this case the physician was in the employee of a medical care scheme that gave incentives to physicians who reduced the costs of medical care under its plan. Mrs. Shea brought a state law tort action under the Minnesota Wrongful Death Statute. She filed against the treating physician, his medical group and the medical health plan and the court found for her that there was a common law duty for a physician to disclose all material information to the patient, including the existence of an incentive plan that would affect the physician’s decision making. It stated:

> From the patient’s point of view, a financial incentive scheme put in place to influence a treating doctor’s referral practices when the patient needs specialized care is certainly a material piece of information. This kind of patient necessarily relies on the doctor’s advice about treatment

\(^{74}\) *Shea-v-Esensten* 107 F.3d 625 (8th cir. 1997).
options, and the patient must know whether the advise is influenced by self-serving financial considerations created by the health insurance provider.\(^7\)

This was the first case to find that a health plan or medical scheme providers as they are known in Kenya have a duty to disclose incentive plans to the subscribers. *Shea* sends a clear message to healthcare practitioners especially physicians, as fiduciaries, that they have a duty to disclose incentive plans that may negatively influence their decision making for an individual’s medical care.

In Kenya we have situations where healthcare providers such as AAR and Avenue Nursing Services also own clinics around the country. They employ physicians and other people to man these facilities. If you are a member of one of these medical schemes it is mandatory that you visit one of their clinics for treatment. This compromises choice and chances are that the physicians have been compromised and the selection of treatment or drugs to be prescribed will be influenced by the healthcare provider.

We can see here clearly that the non-disclosure of the incentive benefits the healthcare plan, because, it prevents patients from receiving alternative treatments which may be better but expensive. It also completely defeats the concept of informed consent and leaves the physician in an indefensible position if the patient is injured.

Physicians can also have financial and personal conflicts of interest in medical research. A patient with a rare condition can make a physician’s reputation as a scientist. In the biotechnology and patent areas, a patient’s tissues can be the basis

\(^7\) Ibid: Shea, 107 F.3d at 628
of extremely valuable commercial products. This was the subject of litigation in the Moore case. This case involved a physician who was treating a patient who was afflicted with hairy-cell Leukemia. During the treatment the physician determined that the patient’s cells would be suitable for making into a cell line with commercial potential. The physician misled the patient into consenting to the numerous medical procedures to facilitate his research work by telling the patient that they were necessarily for treating his medical condition. The patient eventually found out what was going on and sued the physician claiming he was entitled to the value of the cell line derived from this tissue. The court found that whenever a physician has a financial conflict of interest with a patient, the physician’s fiduciary obligations require that the physician make full disclosure of all the relevant information to the patient.

2. Treating Family Members

This is probably the most commonly recognized conflict of interest. It is traditional practice for physicians to treat their colleagues’ families without charge to discourage physicians from treating their own families. This professional courtesy is in recognition of the fact that objective decision-making is critical to medical care and this objectivity is impossible for someone who is emotionally involved with the patient. Treating one’s own family can lead to disharmony and guilt if the treatment is not successful. Although it is not illegal to treat a family member, we think that it may be necessary to limit by legislation the drugs that may be prescribed. Ideally physicians and their family members will seek care from physicians who are not

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6 Moore-v-Regents of University of California, 793 P.2d 479 (Cal. 1990)
close friends or colleagues. This helps objectivity and avoids the conflicts inherent in confiding personnel information to colleagues or friends.

Treatment by other physician also encourages full disclosure of the concern of the patient without any inhibition that helps the physician to diagnose the ailment and therefore provide the correct remedy. If one is being treated by a close relative or friend, the chances and the probability of withholding certain information is very high especially in the case of sexually transmitted diseases.

3. Hospitals

Traditionally doctors were prohibited from owning an interest in a hospital. It was accepted by a consensus of the profession that it would be difficult for physicians to evaluate the need for hospital care objectively if they could financially benefit from putting the patient in hospital.

However, this prohibition has disappeared not because today's physicians have become more objective than their predecessors but rather from the increased profitability of hospital ownership and the fact that in developing countries the governments are not able to provide healthcare facilities for all citizens. The only people who seem to have the money to finance the building of hospitals and clinics are doctors, and businessmen who finance them and oversee them.

The fact that they have a financial interest in the hospital and the desire to have quick returns on their investments intensifies the potential conflict of interest.

In Kenya, the majority of hospitals and clinics are owned by doctors politicians and businessmen. For example, doctors and businessmen own all
Masaba Hospital, Avenue Nursing Home, and Upper Hill Medical Centre in Nairobi. The driving force behind these hospitals is their profitability and therefore the potential for conflict looms. However, the doctors who own them should disclose this interest to their patients to enable them make informed choices when treatments and admissions are recommended.

4. Laboratories

Just as ownership in a hospital potentially interferes with the physician’s objectivity when evaluating the need for hospital care, ownership in a laboratory can encourage the ordering of unnecessary laboratory tests. This is likely to be the case where the physician owns the hospital, the laboratory and the pharmacy. One cannot rule out that the practice of unnecessary medical tests is attributed to direct and indirect financial interest to order the tests. The doctors will even tell you where to go for tests and where to buy the drugs. The extent to which test ordering is influenced by non-medical considerations is a reality and is influenced by financial incentives that are not legal. There are risks associated with ordering unnecessary tests but much greater risks in failing to order a necessary test.

We think at this point it is desirable to examine the doctrine of informed consent and the capacity of a patient to give genuine consent.
CAPACITY TO CONSENT

As we have seen, for consent to be valid, an appropriately informed person who has the capacity to consent to the intervention in question must give it voluntarily. For a person to have capacity, he or she must be able to comprehend and retain information material to the decision especially as to the consequences of having or not having the intervention in question and must be able to use and weigh this information in the decision making process.

However, a patient’s capacity to understand may be temporarily affected by factors such as confusion, panic, shock, fatigue, pain, medication, level of education, religion and or cultural beliefs. However, the existence of such factors should not be assumed automatically to render the patient incapable of consenting. The patient is entitled to make a decision, which is based on their own religious belief or value system, even if it is perceived by others to be irrational, as long as the patient understands what is entailed in their decision.

Competent Adult

It is for this reason and the significance of informed consent that the law is developing in such a way as to ensure that the competent adult has a clear right to receive information about the risks and benefits of a given treatment, and also about alternatives. A competent adult who has capacity has a right to decide whether to accept a treatment or to deny treatment. Physicians must respect this ethical principle; respect their patients, their decisions, their autonomy and dignity.

An irrational decision can be defined as one which is so outrageous in its defiance of logic or of accepted moral standards that no sensible person who had applied his or her mind to the question could have arrived at such a decision.
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78 An irrational decision can be defined as one which is so outrageous in its defiance of logic or of accepted moral standards that no sensible person who had applied his or her mind to the question could have arrived at such a decision
This respect for the autonomy of the patient is what underlies the legal requirement to seek consent prior to any treatment of an adult.

In the United Kingdom, the law requires that in determining if a patient has the necessary capacity to decide whether or not to consent to a procedure, the physician must be satisfied that the patient:

i) possesses the capacity to make a choice;

ii) understands what the procedure is, that somebody has said that he or she should have it and why it is being proposed;

iii) understands in broad terms the nature of the procedure;

iv) understands the principle benefits and risks of the procedure;

v) understands the consequences of not receiving the procedure.\(^\text{79}\)

We have to appreciate here that different decisions require different levels of understanding and an individual may be capable of making one decision but not another. This will depend partly on the relative complexity of the issues involved, the cultural context and the level of education of the patient and or research participant. The level of understanding required for any procedure might in practice, be expected also to depend in part on its risks and benefits. The greater the potential benefits and the less the risk of harm, the more flexible the requirements of an individual's consent, the less the benefit and the greater the risk; the more the stringent should the need for consent be.

We have to mention that even for individuals who are able to give consent fully informed consent is an unattainable goal. This is because the genuineness of consent is defeated by a number of circumstances. This include coercion,

deception, manipulation, deliberate misdescription of information, lack of disclosure of material facts, religious beliefs, cultural beliefs, emergency and conflicts of interest. However, cultural practices must not be accepted uncritically. One has to look at the competing interests and discuss with the patient, research participants or community leaders the best way to pass on the information about a therapy or procedure. The ethically significant requirement is not that consent be complete but that it is genuine. This therefore means that to obtain genuine consent, healthcare professionals must do their best to communicate accurately and in an understandable and appropriate way the purposes and implications of the procedure as well as its risks. They should respect the limits of an individual’s understanding and capacity to deal with difficult information, and allow time for them to ask questions. It may be helpful for consent to be sought in the presence of another person – perhaps, it may be helpful to offer leaflets or other written information presented in a clear, balanced and non technical way with transactions and interpreters available where say English or Kiswahili is not the first language. However we must appreciate that at times particular terms such as placebo, for which there may be no local equivalent concept can be especially difficult to define. There are also situations in developing countries where adults though competent may not have the capacity to give consent. This is because the concept of individual autonomy is not known to some forms of social structures of some societies. In these communities an individual is seen as an integral part of a family or community

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80 Nuffield Council on Bioethics ‘Human Tissue: Ethical and Legal issues’. Paragraph 6.28
81 A medicine that is ineffective but may help to relieve a condition because a patient has faith in its powers: New drugs are tested against placebos in clinical trials. The drug’s effect is compared with the placebo reponse even though there is no pharmacologically active substance in the placebo.
and therefore has to consult elders, parents, spouses or even children before consenting to medical treatment or research. In such situations it may be necessary to obtain the consent of the community leaders before proceeding with any treatment. In some cases women may have to obtain consent from their husbands before they can consent for treatment and or participate in research.\textsuperscript{82}

For example, in some areas of Uganda that hold to traditional, social and cultural values, the head of the immediate family is a man (husband/father) and it is widely recognized and expected that he takes the final decision on all matters including treatment and participation in biomedical research. Family members who do not submit to such decisions may face serious consequences including domestic violence and or divorce.\textsuperscript{83} In such cases then before treatment or participation, permission has to be obtained from the head of the family. However, such permission may be vitiated by emergency situations to safe a life in which case a physician may proceed to offer treatment without prior consent.

An area that causes a lot of concern for adults even if they have capacity to consent is in family planning matters in a male dominated society, where the men insist that they be consulted before their wives are offered family planning services. Here the healthcare provider or researcher is well advised to talk to the couples to get the dual consent of the couple.

As we have stated before, some concepts used in treatment or research may be difficult to explain in an understandable manner, particularly in populations with

\textsuperscript{82} This is true of many rural Kenyan Communities and such a wife may be expelled from her matrimonial home for not seeking the husbands approval or consent.

\textsuperscript{83} Guidelines for the conduct of Health Research involving Human Subjects in Uganda, National Consensus Conference Kampala, Uganda 32 (1997)
entirely different beliefs about the causes of illness who have little familiarity with biomedicine. In such circumstances, the physicians or researchers may need to incorporate local belief systems into the process of providing information. For example they might say: Although I as a doctor believe that the disease that you are suffering from is caused by germs, “I understand that you believe that it is caused by a demon. I respect the fact that you have this belief and I would like you to try this medicine to remove the disease”. The magic word here is to “remove”. Removing the disease is more acceptable to both the physician and the patient whether we think that diseases are caused by germs or a demon. That way a doctor is able to strike a balance and may be able to get consent.

A patient may also refuse to give consent because of religious reasons. Here the patient should be asked probably to sign disclaimers exonerating the doctor. However, the patient’s best interest and public health should override individual religion and other belief.

In Kenya, the age of consent is 18 years and anybody above this age can give consent for medical treatment. There is also no specific legislation on healthcare consent. Therefore obtaining genuine consent is left to common law, institutional guidelines and professional guidelines. Such as the one issued by The Medical Practitioners and Dentists’ Board. These are guidelines that have little legal effect. There is need therefore for official policy on healthcare consent and positive legislation in this area is recommended.

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In summary, most jurisdictions either through statute, common law or guidelines require that physicians obtain genuine consent. That a competent adult makes a choice whether to accept or refuse a therapy. He can only do so in a meaningful manner if the necessary information about the consequences of the choice is provided. It is for the individual to weigh the information in the balance, once a full disclosure has been given to him or her. Any other touching of a patient without their valid consent may constitute the civil or criminal offence of battery. In fact it is an assault.

The Incompetent Adult

Under English law, no one is able to give consent to the examination or treatment of any adult who is unable to give consent for himself or herself (an "incapable" adult). Therefore, parents, relatives or members of the healthcare team cannot consent on behalf of such an adult.\textsuperscript{85}

In situations where the individual is unable, for one reason or another, to offer consent or a refusal, a number of tests have been developed which seek to mandate particular treatment decisions. In such situations, the disclosure of information to the individual may either be meaningless, because the person can't understand it, or irrelevant because the person is for example, comatose. In the circumstances, the emphasis shifts from matters of self-determination and becomes one about how and on what grounds appropriate decisions may be taken for the incompetent person. A number of principles which may legitimize the treatment

\textsuperscript{85} Department of Health, ‘Reference Guide to consent for Examination or treatment’ United Kingdom at Page 12

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which would otherwise be unlawfully are recommended. These are necessity, best interests and substituted judgement.

1. Necessity

It is an accepted practice in medicine and the law allows doctors to proceed to treat patients in case of an emergency, using the doctrine of necessity. In the English Case of *Re F (Mental Patient: Sterilization)*\(^8^6\) Lord Donaldson put the rule this way:

> It is well settled that a doctor who is faced with an unconscious patient is lawfully entitled and probably bound to carry out such treatment as is necessary to safeguard the life and health of that patient notwithstanding that the patient is in no position to consent or refuse consent\(^8^7\)

Thus where no consent has been obtained or where the provision of consent is impossible, treatment may proceed if it is in the best interest of the patient and if it cannot reasonable be postponed until the person becomes capable of giving consent (or, indeed, refusing it). In these circumstances, the treatment must be immediately necessary – not just convenient or desirable – otherwise the doctor acts outside the scope of his or her authority.

The law on necessity in this area has proceeded on the assumption that for something to be necessary it should carry within it the likelihood of saving life or preventing deterioration of health. The general rule is often expressed in reference to two Canadian cases. In the first, *Marshall-V-Curry*,\(^8^8\) the plaintiff argued that the removal of a diseased testicle in the course of other surgery amounted to a battery.

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\(^8^6\) *Re F (Mental Patient: Sterilization)* (1990) 2 ACI (HL)  
\(^8^7\) Ibid at Page 13  
\(^8^8\) *Marshall-v-Curry* (1933 3 DLR 260)
The court, however, held that it would not have been reasonable to postpone the removal until later since it was possibly life-saving. The converse was the case in *Murray-V-McMurchy*\(^9^9\) where the plaintiff was sterilized in the course of a caesarean section. In this case the court felt that the operation could have been delayed in order to obtain the consent (or refusal) of the patient. The Council of Europe expresses the doctrine this way:

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.\(^{90}\)

In the United States of America, federal regulations allow investigators to enroll patients in some medical research without their consent. This is under the Food and Administration Regulations 1996.\(^{91}\) This only applies in circumstances where the patient’s condition is life threatening like a severe head injury and must be unable to say whether they want to be part of a study. They will only be selected if it is not feasible to obtain consent from a relative.

In Kenya, as we have stated before there is no clear legal framework on healthcare consent. The Medical Practitioners and Dentists Board (K) and the National Council for Science and Technology give general guidelines on what may be done on emergency situations and or when carrying out research on incompetents. They advise that life saving treatment may be administered without the usual procedure of obtaining consent and then they go on to say that in such situations consent may be obtained from next of kin, proxy, legal guardian or an independent

\(^9^9\) *Murray-v-McMurchy* (1949) 2 DLR 442
\(^{91}\) Karthy Kasten: *New York Times* 11th May 1996
senior doctor. These guidelines are ambiguous and can be interpreted differently by
different people depending on the circumstances. For example who is next of kin.
It is necessary to define such terms to avoid ambiguity.

2. Best Interests

Where the doctrine of necessity is not applicable, there may still be
circumstances in which it is lawful to proceed with an intervention where consent of
the patient cannot be obtained. This would be authorized on the basis that
treatment is in the “best interest” of the individual. However such decisions cannot
be taken by relatives where the patient is an adult since they have no legal
standing.

In Scotland, the appointment of a ‘Tutor Dative’ is used to authorize a person
to make treatment decisions for the incompetent, although more commonly, it
would be expected that the authority of a court would be sought, particularly in
sensitive matters. The court would therefore be invited to exercise its *Parens
Patriae* jurisdiction, that is, its residual power to act on behalf of an incompetent
person, protecting his/her best interests.

What exactly is meant by a patient’s best interests? The crucial insight was
articulated by Butler-Sloss L. J. in *Re MB (Medical Treatment)*\(^2\) when she said:

> Best interests are not limited to best medical interests.

This means then that a patient’s best interests involves a welfare appraisal in
the widest sense, taking into account, where appropriate, a wide range of ethical,

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\(^2\) *Re MB (Medical Treatment)* (1997) 3 FLR 426 at Page 439
social, moral, emotional and welfare considerations. Best interests encompasses medical, emotional and all other welfare issues.\textsuperscript{93}

This has since been elaborated in what we think are two fundamental important recent cases which involved issues of removal of life support machines and artificial nutrition and hydration. The two cases are \textit{Theresa Marie Schindlerin Schiavo-V-Michael Schiavo}\textsuperscript{94} and the English \textit{Case of Oliver Leslie Burke-V- The General Medical Council and Others}.\textsuperscript{95} These two cases raise issues of great importance to medical law and ethics. In particular, these cases focus on the extent to which we should respect the patient’s autonomy, the personal autonomy which the law now recognizes and demands that individuals be given a choice of medical treatment, the choice of how we are to live and how we are to die and that such choices should be left to the individual. In the Burke case the court gave the following guideline in respect of a patient’s best interests:

> Doctors have an ethical obligation to show respect for human life, protect the health of their patients, and to make their patients best interests their first concern\textsuperscript{96}

What this means then is that best interests means offering those treatments where possible benefits outweigh any burdens or risks associated with the treatment and avoiding those treatments where there is no net benefit to the patient.

Mr. \textit{Leslie Burke} who is confined to a wheelchair, suffers from cerebella ataxia, a disorder of the nervous system that slowly robs people off coordination and movement, although it does not affect their mental faculties. Eventually, sufferers

\textsuperscript{93} Re A \textit{(Male Sterilization) (2000) FLR 549 at Page 555}
\textsuperscript{94} \textit{Theresa Marie Schindlerin Schiavo-v-Michael Schiavo}. In the United States Court of Appeals for the Eleventh circuit No. 05-11556 March 2005
\textsuperscript{95} \textit{Oliver Leslie Burke-v- The General Medical Council and Others} (2004) EWHC 1879 (Admin)
\textsuperscript{96} Ibid at P.225
loose the ability to communicate. Mr. Burke brought the initial case because he was concerned that the guidelines issued by the General Medical Council (GMC) of England meant that when he lost the capacity to communicate, medical staff could effectively starve him to death against his wishes. In 2004, he won a landmark ruling, which supported his right to artificial nutrition and hydration. However, the GMC appealed, saying doctors would be put in an impossible position. In a landmark ruling delivered on 28th July 2005 the General Medical Council won the appeal. The Court of Appeal ruled that doctors have the right to withdraw food and drink from dying patients if they believe it to be in their best interests.

The concept of “best interests” is a contested concept and although the courts, undoubtedly, by one route or another, have the authority to make treatment decisions for the incapacitated person, acting in their best interests, it is by no means clear precisely what such “best interests” are and how they are to be assessed. The concept is somewhat woolly. How can it be applied in a developing country such as Kenya where a large number of the citizens have no access to courts and applications may take years to be determined. In such situations we recommend that consent be obtained from the next of kin, legal guardian or an independent senior doctor with the hope that they will act in the best interest of the incompetent though this cannot always be guaranteed.

3. Substituted Judgement

If neither necessity nor best interests is sufficient to guide us where there is no evidence of consent, one further test, that of substituted judgement, could be used. Courts in the United Kingdom have been reluctant to employ this test, although it has found favour in other jurisdictions, most notably in the United States. This test is applied where no formal evidence of consent is available, and is
designed to assess what the individual concerned would have chosen had they been in a position to do so. As one court put it:

In essence, an attempt is made to determine the actual interests and preference of the mental incompetent. This, it is thought, recognizes her moral dignity and right to free choice.  

However, we think this test is fundamentally flawed since the assessment of what would have been chosen is, in the absence of real evidence equivalent to guesswork. In the United States Case of In re Storer for example, it was described as being an unrealistic standard to apply.

Nevertheless it has found favour in a number of US cases, subject to the laying down of strict criteria. However, in the celebrated case of Cruzan-V-Director, Missouri Dept. of Health etal the court was unwilling to permit the removal of life sustaining treatment simply on the assertion of Nancy Cruzan’s parents that she would not have wished to survive in that condition. Of course this position has now been overturned by the Terri Schiavo Case where the court accepted evidence from Terri’s husband to the effect that she had told him that she would not like to be kept alive in a persistent vegetative state and allowed the removal of the feeding tube that kept her alive and she died a few days later. In accepting this evidence the court was in effect applying the substituted judgement test.

The substituted judgement test would find favour in developing countries such as Kenya. This is because the concept of individual autonomy is largely absent from the social structures of these communities. An individual is seen as an integral

97 Per La Forest, J., in Re Eve 31 DLR (4th Edition) at P. 27
98 re Storer 420 NE 2d 64 (NY 1981)
99 C.F. Re Hayes 608P 2d 635 (Wash 1980) and Re Grady 405 A 2d 851 (Md, 1979)
100 Cruzan-v- Director, Missouri Dept. of Health etal 497 US 261 (1990)
part of a family or a community and therefore the concept of substituted judgement can easily be promoted as it is in line with the social structures of these communities. It is not uncommon to hear elders saying (when somebody is sick and incompetent to communicate) that his wishes were such and such. We therefore would recommend the promotion of this concept.

In general, although the substituted judgement test focuses on what has been said to be critical – namely the wishes of the individual him or herself, it is notoriously difficult to satisfy and may be open to abuse.

Children

In most countries the capacity of children to consent to medical treatment is constrained by statute and common law, although, the age at which capacity to consent is conceded may differ from country to country.

The legal uniqueness of children may be said to have three treads to it. The first of course is consent to medical care. Children may not legally determine their own care, neither are parents fully empowered to control their children’s medical care. The second is communication to a doctor or healthcare provider. Very young patients are unable to communicate their medical needs effectively to the physician, and finally childhood immunizations are at the frontline in protecting society from epidemic communicable diseases. Immunization with the potential risk of serious squealer creates a conflict for consent between the child’s individual medical care needs and the protection of society.
In the early days, parents had almost unlimited power over their children. Physical abuse of children was tolerated and neglect, even to the point of death was common. Children were treated as the property of their parents (father never mother). However this has now changed and protective children laws have been enacted that attempt to protect children from abuse and neglect. These laws together with the public health laws, and court decisions on reproductive rights have greatly limited parental rights to deny children medical care.

In the United State of America children under 18 years old do not have the right to consent to their medical care.101 Unless the parent’s legal rights have been terminated, the parents of a minor have the sole authority to consent to medical care for the minor. In most states, if the parents are married to each other, they have an equal right to consent to medical care for the children of that marriage. If the parents are divorced or were never married, the parent with legal custody of the child may have the sole right to care for the child. This of course does not give the physician the legal right to force questionable care on a minor, such as sterilization at the parents’ request.

In England the capacity of children to consent to medical treatment is apparently very straightforward. Under the age of sixteen it is covered by the common law which is stated most clearly in the case of Gillick-V-West Norfolk and Wisbeck Area Healthy Authority.102 This case broadly held that a child under the age of sixteen years would have the capacity to consent to medical treatment if he or she was of sufficient maturity to understand the nature and consequences of that

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101 Richards E.P. Ill and Ratbun K.C., “Medical Care Law” (Garthersburg, Maryland: Aspen Publishers, Inc, 1999), 219
102 Gillick-v-West Norfolk and Wisbeck Area Healthy Authority (1985) 3 All ER 402
consent. (Gillick competent). Over the age of sixteen, the young person is subject to the terms of the Family Law Reform Act 1969 which says in Section 8(1):

The consent of a minor who has attained the age of sixteen years to any medical treatment which, in the absence of consent, would constitute a trespass to the person, shall be as effective as it would be if he were of full age; and where a minor has by virtue of this section given effective consent to any treatment it shall not be necessary to obtain any consent for it from his parent or guardian.

Therefore as a child matures he or she acquires the capacity to agree to treatment on his or her own behalf without parental consent. We need to note however, first, that the decision as to the competence of the child under the age of sixteen years is one which is generally made by doctors, although on occasions courts have been asked to adjudicate, usually, but not exclusively when the child wishes to disagree with the clinical recommendations by refusing treatment.103

Recent court decisions have interpreted this to mean that children may consent to treatment but that their refusal of treatment may not be deemed valid in the face of a lawful consent given by another person authorized to act.104

Second, there must be some doubt what a child can consent to. The English legislation specifically refers to "treatment" although the Gillick case concerned the question of whether or not children could; receive contraception without their parents being involved in the decision. Arguably, contraception stands as a different form of medical intervention from 'treatment' although the boundaries of what treatment is have to an extent been boarded by the judgement in Airedale NHS

103 See Elliston S; 'If you know what is good for you: Refusal of Consent to Medical Treatment by Children, in McLean, S A M (ed) Contemporary issues in "Law Medicine and Ethics“ (Aldershot, Dartmount, 1996)
104 Re W (a minor) (Medical treatment) (1972) All ER 627
Trust-V-Bland\textsuperscript{105} in which the House of Lords seemed content to hold that artificial feeding and hydration amounted to treatment.

In Kenya a child means "any human being under the age of eighteen years."\textsuperscript{106} Under the Children's Act 2001 every child has a right to health and medical provision shall be the responsibility of the parents and the government. The inference of this is therefore that the age of consent in Kenya is eighteen years and parents or legal guardians are required to give consent for those patients under the legal age. However this age of consent may create problems in situations such as the provision of family planning services. However we recommend here that the doctor should carefully counsel both the child and the parents.

The Code of Professional Conduct and Discipline issued to medical practitioners by the Medical Practitioners and Dentists' Board (K) recommends that in such situations consent must be obtained from the legal guardian or parent,\textsuperscript{107} and in any other case it must be in the child's best interests.

We must admit here that official policy and guidelines in Kenya are lacking in this area and recommend that a legal framework be enacted which will go a long way to solve some of the conflicts that may arise which include, conflicts between parents, children and religious beliefs.

1. Conflict between Parents

Children can be pawns in marital battles. This becomes an issue in medical care if the child is being abused or if the parents disagree on medical treatment. If

\begin{itemize}
\item \textsuperscript{105} Airedale NHS Trust-v-Bland (1993) / AH ER 821
\item \textsuperscript{106} The Childrens Act 2001: Section 2
\item \textsuperscript{107} "The Code of Professional Conduct and Discipline", (5\textsuperscript{th} Edition), The Medical Practitioners and Dentists Board (K) (2003)
\end{itemize}
the disagreement over medical care threatens to escalate into neglect or physical harm, this must be reported to the child protective services.

The most difficult cases are those involving disputes over elective care, where the parents do not agree on the treatment. Legally, consent from one parent is sufficient. However, if the physician has been refused consent by one parent, it is less clear as to what the physician should do. We recommend that in such situations the physician should proceed to treat the child provided that it is done in the child's best interest and may be thereafter apply to the court for wardship.

2. Conflicts between Parents and Children

Here we have in mind those cases where there are attempts by parents to force care on mature minors. The most common scenario involves involuntary psychiatric care for an allegedly drug abusing or crazy teenagers. Here the doctors or physicians have an ethical obligation not to allow psychiatric care to be used to manipulate or punish a recalcitrant child. Legally, the child could sue for malpractice against the physician who recommends unnecessary psychiatric care.

3. Religious Objections to Medical Care

This is one of the most important arrears in the law governing consent to medical treatment by minors, where religious beliefs of the parents were once paramount; the child's right to life and health now takes precedence over the parent's right to freedom of religion. An adult Jehovah's Witness, for instance may have the right to refuse transfusion, even if it means certain death. That same person does not have the right to refuse transfusion for a child who will likely die. If

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a parent refuses necessary care for a child, the doctor should ideally proceed with the care regardless of the parent’s objections. The justification for this is the same as the emergency exception to consent or proceed with the care just as if the parents are unavailable.\textsuperscript{109}

In summary therefore, children are given some rights to agree to medical treatment, although the boundaries of what they can consent to are not always clear. Those with proxy authority, for example parents or courts, must act in the ‘best interests of the child’, however these interests must be defined by law and this is lacking in Kenya.

Mentally Incapacitated People

Questions concerning the treatment of mentally incapacitated people and people with learning disabilities have arisen recently. In the United Kingdom a series of cases have held that it can be in the best interests of a woman with learning disabilities to be sterilized.\textsuperscript{110} These non-consensual sterilization cases have raised considerable concern not least because of the presumptions about the sexuality and or interest in parenting of mentally incapacitated people but because they have considerably stretched and questioned the concept of ‘best interests’.

Mild disability will not necessarily mean that the individual cannot consent on his or her own behalf. However, the more severe the disability the more difficult the situation becomes.

To enable us address the conceptual and practical bases from which intervention may be authorized it is instructive for us to look at two legal systems

\textsuperscript{109} Holder A.R. “Minors rights to consent to Medical Care” JAMA 1987;257:3400-3402

namely United Kingdom legal system and the Kenyan legal system, in order to appreciate the complexities that arise for informed consent.

In the United Kingdom there have been a number of cases concerning the position of persons with learning disabilities in respect of medical intervention. These have primarily focused on questions concerning the lawfulness or otherwise of non-consensual sterilization, generally for contraceptive purposes and genetic screening. Authority of the court has been sought and obtained for non-consensual sterilization on a number of occasions\textsuperscript{111} although it was refused in the case of \textit{Re D},\textsuperscript{112} where the handicap was not sufficiently severe and seemed to improve. In one successful application, Lord Hailsham put the situation as follows:

There is no doubt that in exercise of its wardship jurisdiction the first and paramount consideration is the well-being, welfare or interest (each expression for a purpose, synonymous) of the being concerned, that it is the ward herself or himself. In this case I believe it to be the only consideration involved\textsuperscript{113}

In another case the court declared lawful treatment which they considered to be in the best interests of the incompetent adult. This was in the case of \textit{Re F},\textsuperscript{114} where Lord Brandon said:

...a doctor can lawfully operate on, or give other treatment to, adult patients who are incapable, for one reason or another, of consenting to his doing so, provided that the operation or other treatment concerned is in the best interests of such patients. The operation or treatment will be in their best interests if, but only, it is carried out in order either to save their lives or to ensure improvement or prevent deterioration in their physical or mental condition.

\textsuperscript{112} Re D (a minor) (Wardship: Sterilization) (1976) 1 All ER 326
\textsuperscript{113} Re B (a minor) (Sterilization) (1987)
\textsuperscript{114} Re F (Mental Patient: Sterilization) (1990) 2 AC1
From these judgements in the United Kingdom, it is presumably the case that the English courts feel able to approve a variety of interventions so long as they are felt to be in the best interests of the person concerned, whether or not these interests are always manifested to the observer. Clearly definition of best interests is critical to the lawfulness or otherwise of the procedure and equally clearly, it is difficult to define. It is for this reason that the Law Commission recommended in 2004 that a mental capacity legislation be enacted to repeal part of the Mental Health Act 1983. The mental capacity legislation was to make new provision relating to persons who lack capacity and is yet to become law.

In Kenya treatment of persons suffering from mental disorder is governed by the Mental Health Act CAP 248 Laws of Kenya and consent guidelines issued by the Medical Practitioners and Dentists Board (K). The Mental Health Act\textsuperscript{115} defines a person suffering from mental disorder as follows:

\textit{means a person who has been found to be so suffering under the Act and includes a person diagnosed as a psychopathic person with mental illness and person suffering from mental impairment due to alcohol substance abuse.}

Under Section 10 of the Mental Health Act a person who has attained apparent age of sixteen years may voluntarily submit himself to treatment for mental disorder and under section 10(3) proxy consent is provided for and under section 13(2) a health care provider has to report to the district mental health council for directions on treatment where the legal guardians or parents are incapable of performing or neglecting their parental responsibilities or refusing consent for a patient who is less than 16 years.

\textsuperscript{115} CAP 248 Laws of Kenya
Section 14 of the Mental Health Act CAP 248 provides for treatment without consent for involuntary patients as long as this is done in their best interests. For an adult person who is deemed to be mentally incompetent to make his or her own treatment decisions, a doctor must act in that patients best interests. As we have stated before, best interests may vary according to the nature and degree of certainty of the information, the person’s capacity for understanding and acting on the information and his or her wishes, social and family contexts of the mental patient.

We have to mention here that there is no universally accepted characterization of mental disorder. Widely used definitions are those in current use by international systems of classification. Thus, to quote, mental disorder “is not an exact term, but is used to imply the existence of a clinically recognizable set of symptoms or behaviour associated in most cases with distress and with interference with personal functions. Social deviance or conflict alone, without personal dysfunction should not be included in mental disorder as defined here.”

Other concerns on Capacity

We wish briefly to make a comment on other concerns regarding capacity that face health care providers. These situations include, duration of consent, temporary incapacity, and fluctuating capacity.

1. Duration of Consent

Where a patient gives valid consent to an intervention, in general, that consent remains valid for an indefinite duration unless it is withdrawn by the patient.

However, if new information becomes available regarding the proposed intervention (for example new evidence of risks or new treatment options) between the times when consent was sought and when the intervention is taken, then it is important that the physician or doctor informs the patient and reconfirms their consent where possible with them or their legal guardian. Of course this may not be possible in all situations. Where they must proceed, they must only do so in the best interests of the patient, and only in order to save a life.

2. Temporary Incapacity

An adult who usually has capacity may become temporarily incapable, for example whilst under general anaesthetic or sedation, or after a road accident. In such situations the doctor is allowed to proceed if the interventions are necessary and no more than is reasonably required in the patient’s best interests pending the recovery of capacity.

3. Fluctuating Capacity

It is possible for capacity to fluctuate. In such cases it is good practice to establish whilst the person has capacity his views about any clinical intervention that may be necessarily.

The above concerns may not cause much concern in developing countries such as Kenya where individual autonomy is largely unknown. In such cases, family, community leaders or friends who are close to the patient will be the best people who can advice the physicians on the patient’s needs and preferences.

However, it must be noted that in all cases of individuals who are incompetent to give informed consent and therefore rely on other people designated
to give such consent on their behalf, the following concern must be recognized: The designated person can be manipulated and give consent which would not be in the best interest of the patient or research persons. Under such circumstances it may be necessary to device a procedure under which the courts play a role in authorizing the designated person to give consent to avoid manipulation.

THE FORM OF CONSENT

It is clear that the quality of a decision hinges not on how it is shown, but rather on how it is reached. If sufficient information has been provided, the competent patient can make a legally valid decision which can be demonstrated in any form whatsoever. Thus, there is no general requirement in law that consent be in writing.

Consent for medical treatment may be in any of the following: It may be implied, expressed, written or anticipated.

1. Implied Consent

In some cases implied consent is accepted and acted upon, for example where a patient holds out an arm for an injection. However, it should be born in mind that even this consent is not legally effective if it does not follow from adequate information disclosure, unless the implication is that the patient knows or understands the information which has not been disclosed and which is central to the validity of the decision.
2. Expressed Consent

Equally, consent may be expressed that is, the patient may verbally authorize therapy to go ahead. However, in this situation also, the legal validity of the purported agreement depends on their having been disclosure of the relevant information.

3. Written Consent

In more serious interventions, although there is no general requirement that consent be in writing in the jurisdictions that we have studied namely United States of America, United Kingdom and Kenya. In practice, however, this is what occurs. For surgical intervention, it is standard practice for a written consent form to be obtained and indeed the existence of such a form is normally required as part of the pre-operative checklist before a surgeon operates.

In the Kenyan case of J.A.O-V-Home Park Caterers Ltd and others the plaintiff has sued a doctor for conducting an HIV Test on her without her prior, informed and express consent, which she prays, violates the plaintiff’s rights to privacy and other fundamental rights enshrined in the Constitution of Kenya. on his part the doctor avers that the diagnosis and treatment was done with the patient’s express consent. As at the time of writing this paper this matter was being deliberated on and the outcome will give judicial direction on medical consent in Kenya.

117 J.A.O-v-Home Park Caterers Ltd Civil Suit No. 38 of 2003 (O.S)
118 Sections 70.74,82 and 84 of the Constitution of Kenya
There are a number of reasons given for preferring written consent. First, it may be felt that the gravity of the procedure requires a record that agreement was given. Second, the form itself can provide or reinforce specific and valuable information for the patient thus serving as part of the process of informing him or her. Third, it may be felt that a written agreement adds probity to the claim that consent was infact given, although it must be born in mind that a written consent is still capable of being challenged should it emerge that necessary provision of relevant information was not made.

It would seem, therefore, that in matters of significant risk or particular sensitivity it is a pragmatic, if not a legal rule that consent is given in writing. Although not unchallengeable, it nonetheless remains the best evidence that an agreement was actually provided, and therefore that the doctor’s actions are *prima facie* lawful. It reminds doctors of the need to provide information, facilities or a free and knowing decision making by the patient, and its existence may assist the doctors should their behaviour subsequently be challenged, by creating a rebuttable presumption that the correct procedures have been undertaken.

**Anticipated decisions**

In some situations, the individual’s agreement may not be recorded contemporaneously. Individuals may wish to anticipate certain events and provide guidance to their doctor’s as to which treatment they would or would not accept. These statements are referred to as advance directives or ‘living wills’ although the British Medical Association\(^{119}\) prefers to refer to them as advance statements, thus

\(^{119}\) "Advance statement about Medical Treatment. (London BMJ Publishing Department, 1995)"
avoiding any implication that they must in all cases be followed by the treating doctor.

Such statements are of interest as demonstrating that a considered judgement should be respected even once the person becomes incompetent. Failure to respect such declarations may result in litigation as in the Canadian case of: *Malette-V-Shulman*\(^{120}\) in which a Jehovah’s Witness successfully sued in assault the doctor who had, in full knowledge of the existence of her objection to blood transfusion, nonetheless proceeded to transfuse.

In developing countries this concept is unlikely to find favour. In African societies to anticipate sickness or illness is unheard off, let alone talk about it. However, in consideration of recent development in medical technology we propose that a statutory framework be enacted to direct these advancement especially on the right to life.

In general therefore, it is presumes that the best evidence of the individual’s wishes will come from a written statement, although there is no legal requirement that the statement should be in writing. Even better evidence however may be given by way of statements given in evidence. For example in *Re C*\(^{121}\) an English court held that a man who was diagnosed as suffering from paranoid schizophrenia was competent to refuse life-saving treatment and also endorsed his verbal refusal of the treatment at any and all times in future, whether or not he was then competent.

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\(^{121}\) *Re C* (1992) 4 All, ER 649
DOCUMENTING CONSENT

This is an important area in the informed consent process which we tried to
discuss with some of the doctors at various hospitals that we visited to have access
to their consent forms\textsuperscript{122}. Our attempt to raise issues regarding consent forms at
the Kenyatta, Nairobi, Mater, Avenue Nursing, Armed Forces Memorial and Aga Khan Hospitals resulted in the finding that most of the doctors were reluctant to
discuss the issue of informed consent either because they did not want to be probed on their understanding of the doctrine of informed consent or they just did not know anything about it.

However, we must appreciate that there are goals to achieve when documenting informed consent. The more important is using the process of documentation to ensure that the physician and the patient have the same understanding of the care being rendered, its risks, benefits and alternatives. The second goal is to document this understanding in such a way that a third person such as a court can determine both what the patient was told and whether the patient had some reasonable understanding of the implication of what was told.

It is true that most of the literature on informed focuses on the consent forms. However, informed consent is more than just getting a form signed. A proper informed consent starts with a discussion between the physician and the patient. In this discussion, the physician discusses the risks of the proposed

\textsuperscript{122} Discussion with Dr. Waitara, Dr. Gachiri at the Nairobi Hospital on 14\textsuperscript{th} April 2005 and Dr. Ayugi at the Armed Forces Memorial Hospital on 18\textsuperscript{th} April 2005 and Dr. Were and Dr. Manguyu at Mater Hospital on 30\textsuperscript{th} May 2005. The consent forms which we secured in the process are in Appendix I.
treatment and its alternatives. Most importantly the risks and alternative must be discussed in the context of the patient’s prognosis.

1. The Form of the Documentation

There is no single best way to document consent. In some situations such as in an immunization clinic, having the patient sign a pre-printed consent form is optional. In other situations the form of documentation must fit the circumstances of the actual transaction between the physician and the patient.

2. Blanket Consent Forms

The worst solution to documenting informed consent is the form that blankets all possibilities. The typical blanket forms recite that the physicians and or his or her designers may do what they think is necessary. These forms usually contain language about how the doctor has discussed the treatment with the patient and that the patient has had an opportunity to ask questions when infact the doctor has not discussed at all. Such forms are meant to protect the physician from accusations of battery. As sole records of consent, these forms are worthless. In Appendix (I), we have some specimen consent forms that are in use in some hospitals in Kenya. At best in our view they are tools to protect the doctors and not to record genuine consent.

3. Illiterate Patients

The ritual of the patient’s reading and signing a form or chart note is meaningless if the patient is illiterate. In such situations a translator who is familiar
with the patient’s dialect and medical terms is required. Here we must appreciate that the mechanisms of obtaining informed consent evolved in the developed countries where most of the population is literate and generally aware of modern health practices. To use such forms to obtain consent from a non-literate community that operates on different concepts of health and disease would be an exercise in self-deception.

In some cultures, the patient’s only experience of signing forms may be associated with tax documents or court proceedings. Thus signing forms may have negative connotations making otherwise willing patients refuse to sign them. We recommend therefore, that consent forms be simple, concise, and clear, in a language that the patient understands and appropriate to the cultural contexts of the patient.
CHAPTER III
CONSENT FOR MEDICAL RESEARCH

The conduct of research related to healthcare is subject to a wide range of national and international guidance, guidelines, declarations and regulations (which we will call guidance except for those regulations which have the force of law). The international guidance has formed the basis for national guidance adopted in many countries. In general the guidance covers a wide range of activities in research involving human participants.

Interestingly, there has also been more medical legal scholarship on the conduct of medical research involving human subjects than almost any other consent topic in contrast to the nearly complete lack of litigation alleging injuries from improperly conducted research. Medical research is controversial because of the abuses that have occurred in the not too distant past. This range from the medical experiments conducted by the Nazis to the Tuskegee syphilis experiment\(^\text{123}\) conducted by the United States Public Health Service, these abuses resulted in the promulgation of two major international guidelines and extensive national regulations. Any patient injured by an experiment that violates these guidelines or regulations can sue the physician for medical malpractice.

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INTERNATIONAL GUIDELINES AND INFORMED CONSENT

Two international guidelines govern the conduct of medical research involving human subjects. These are the Nuremberg Code which arose from the Nuremberg Trials of Nazi War criminals accused of conducting medical experiments on prisoners that caused great suffering and the World Medical Association Declaration of Helsinki in 1964. In this chapter, we review the broad framework of these two guidelines as they relate to the doctrine of informed consent and research involving human participants.

1. The Nuremberg Code

The Nuremberg Code was formulated in 1947 following the Nuremberg trials, at which a number of Nazi researchers were convicted. The trials revealed that research on human beings had been conducted by Nazi physicians in German without due regard to the welfare or, indeed, the survival of the participants. The Nuremberg Code has ten requirements. The first requirement underscores the importance of voluntary consent of the human subject before being made to participate in medical research and states:

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, overreaching, 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. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should

\[124\] Supra: Footnote I
\[125\] Infra: Appendix II
be made known to him the nature, duration, and purpose of
the experiment; the method and means by which it is to be
conducted; all inconveniences and hazards reasonably to be
expected; and their effect upon his health or person which
may possibly come form his participation in the experiment.
The duty and responsibility for ascertaining the quality of the
consent rests upon each individual who initiates, directs, or
engages in the experiment. It is a personal duty and
responsibility, which may not be delegated to another with
impunity.

We can see therefore that the Nuremberg Code sets forth principles designed
to protect human subjects from abuses related to medical research. It's statement
of the ethical framework for medical research is considered to be the policy behind
the World Medical Association's Declaration of Helsinki in 1964 which sets out
principles to be observed in research involving human subjects. It was endorsed by
the World Medical Association (WMA) in 1964.

2. The Declaration of Helsinki

The Declaration of Helsinki was published by the World Medical Association in
1964. The Declaration which has been revised five times\textsuperscript{126} to date sets out the
principles to be observed in research on human participants and has become the
cornerstone of research related to healthcare. Its standing is such that the
principles enshrined in it have been incorporated into many of the forms of guidance
that have subsequently been drawn up to govern the conduct of research related to
healthcare for both international guidance and national guidance.

When the Declaration of Helsinki was published in 1964, the scope of its
provisions was considered to be comprehensive. However, it was soon recognized

\textsuperscript{126} Infra: Appendix II and Table I
that it did not include concerns of research in developing countries, it did not adequately provide for guidance relating to consent and the review of ethics of research, the involvement of pregnant women in research, possible conflicts of interest, data, and confidentiality and the publication of research results. It is to address these concerns that the various revisions have been made.127

According to the current version (2000) of the Declaration, any research carried out involving human participants must be based upon sound scientific principles, and according to a properly formulated protocol for the study that has been subjected to the scrutiny and advice of an independent committee (a research ethics committee). The Declaration recognizes the fact that most interventions – diagnostic, therapeutic and preventive, and especially those involving biomedical research, involve hazards and that issue of risks and hazards must be addressed. It notes that when research involves healthy volunteers, special care must be taken to determine if the objective of the research outweighs the inherent risks and burdens to the participants.

Paragraphs 8, 20, 21, 22, 23, 24 and 25 of the Declaration deal with the doctrine of informed consent and are relevant to our study.128

The Declaration in Paragraphs 8, 10, 20, 21, 22, 23, 24, and 25 provides that, participants always have the right to safeguard their integrity and their privacy. The importance of these considerations is that they lead on to the central requirement: That before research related to healthcare can be carried out on humans, the participants must first be adequately informed about all the relevant aspects of the

127 Anon (1999), Helsinki Declaration revision: “Bulletin of Medical Ethics” (Anon: 146), 3-5
study including its aims, procedures, attendant risks, hazards and the potential benefits and discomforts and their consent sought. Informed consent must be given by the participants.

The core value of these international guidelines is that medical research cannot be performed without the freely given (uncoerced) consent of the potential subjects: These guidelines do not have the force of law, but they set the moral tone for all medical research, including research that is unregulated by a country’s law. These guidelines are admissible in court as evidence of the proper standard of care for medical experimentation.

However, over recent years, there has been an increased criticism of much of the guidance which exists on three counts. First, while the guidance sets out the fundamental ethical principles relevant to the conduct of clinical research on human participants, it is too general in nature to address many of the specific and often controversial issues that are raised by research. For example, guidance about the standards of care which should be used in clinical trials and the availability of treatment after a trial is over is set out in very general terms and can have varying interpretations.

Secondly, the various forms of guidance, whether international or national, in many instances do not take into account the special circumstances that attend research undertaken in developing countries and sponsored by developing countries. In addition, developing countries often have little or no relevant national guidance. In such situations where research is externally sponsored, there is a danger that the
conduct of the research may fail to reflect the cultural and social values of those from the developing countries who participate.

Thirdly, in many developing countries the concept of individual autonomy may be absent from the social structures of some societies. An individual is seen as an integral part of a family or community and therefore has to consult elders, parents, spouses or even children before consenting to any medical or surgical procedure. In some areas, it may be the case that consent has to be obtained from the community leaders before any research is carried out. Researchers should be aware therefore of the tension which may arise in communities simply as a result of asking for such consent. If the community leaders are not consulted a family may as well be expelled from their village for not seeking the approval of the village elder. In some communities like the Masai of Kenya, women have to obtain the consent of their husbands to participate in research.

The guidelines also do not address whether research is acceptable in situations where the community elders or family members consent on behalf of participants who, in the developed world, would be considered capable of consenting for themselves.129

The guidelines also do not take into account certain cultural beliefs as regards consent for research. For example, in some communities in Kenya (the Giriama and Kisii) there is a widespread belief that a person’s blood contains his or her spirit and if taken in any quantity it is feared that the spirit is also lost. This is because it is believed that whoever takes the blood is believed to control the spirit and body of

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129 The question of who gives consent to the inclusion of a country in clinical trials where entire villages or communities, rather than individuals, is a difficult one.
the individual whose blood taken. In some communities there is often a greater reluctance to provide samples of faeces. This is because of the belief that the faeces may be used for witchcraft.

It is in recognition of this that the Council for International Organisation of Medical Sciences (CIOMS) in collaboration with WHO, recognized the special circumstances which arise when applying the Declaration of Helsinki to research undertaken in developing countries and proposed guidelines to address them in 1982. These guidelines sought to direct the conduct of research involving human participants in a way that would recognize the social, economic, legal, regulatory and administrative arrangements that exist in developing nations. ¹³⁰

These proposed guidelines have been reviewed so as to take into account the ever increasing transitional nature of research, the ethical issues that have arisen from the advent of HIV/AIDS pandemic, large scale clinical trials of medicines and vaccines. In 1993 WHO/CIOMS published the “International Ethical Guidelines for Biomedical Research Involving Human Subjects”, which recommends the formation of research ethical committees by countries. This document was adopted at a Health Research Ethics in Africa Seminar in Arusha, Tanzania on the 15th January 2001, as the minimum requirement for ethical biomedical research involving human subjects in Africa. However, this document has not received widespread utility in Africa as some countries have not constituted ethical committees.

In conclusion, we recommend that, in circumstances where consent to research is required, genuine consent to participate in research must be obtained

from each participant. In some cultural contexts it may be appropriate to obtain agreement from the community or assent from a senior family member before a prospective participant is approached. Sensitivity to other cultures is necessary. However, culture cannot override the central requirements of respect for persons, which requires that we refrain from conducting research without consent. This is a fundamental principle, which seeks to promote and safeguard the integrity, and privacy of an individual.
CHAPTER IV

INFORMED CONSENT AND HUMAN TISSUE

The development of modern medicine has relied on the availability of human bodies for students to practice upon. When a doctor is treating a patient it is invaluable for that doctor to have a working knowledge of the physiological functions of the body and how it works.

In the Eighteenth and Nineteenth centuries medical schools in United Kingdom were only allowed to use the bodies of executed criminals for dissection purposes and with the growing numbers of students, it became clear that there were not enough executions to supply the demand. The demand became so acute that there flourished a macabre trade in bodies. Medical schools would pay for bodies that could be supplied without asking questions about their provenance. Thus the practice of body snatching arose, one of the more famous examples being that of William Burke and William Hare who practiced their trade as body snatchers, or resurrectionists, in Edinburgh in the early nineteenth century. Burke and Hare however did not simply rely on providence to obtain access to bodies, instead they began to guarantee their supply by murdering people.

The scandal that followed the discovery of the practices of Burke and Hare led to the passing of legislation to provide for the supply of bodies for medical purposes, the Anatomy Act 1832 of the United Kingdom.

Since then, there have been a number of pieces of legislation dealing with particular issues in the United Kingdom and currently the two main pieces of legislation governing the removal, retention and use of human organs are the *Human Tissue Act* 1961 and the Anatomy Act 1984.

In Kenya the story is not much different. The University of Nairobi Medical School which was started by Professor Joseph Mungai in 1967 did not have bodies to be used by students when the school started. It took the courage of Professor Mungai to take his vehicle and drive all the way to Makerere University Uganda to request for a donation of 10 bodies for teaching purposes.¹³²

The collection from mortuaries of unclaimed human bodies for use in teaching human anatomy is controlled by the *Anatomy Act*¹³³ which was enacted in 1968 and *The Human Tissue Act*¹³⁴ which was enacted in 1967 deals with uses of parts of bodies of deceased persons for therapeutic purposes and purposes of medical education and research.

These legislations both in the United Kingdom and Kenya exist to provide a framework within which physicians or doctors might be able to more effectively ply their trade and make use of the material they encounter to better understand the workings of the human body. The ability to retain human tissue for analysis and comparison has been common practice because of the utility of actually showing the effects of disease or damage upon those tissues to doctors in training. What has not been common practice is informing the patients or relatives of the dead persons of the extent of retention or ensuring that the reasons are properly understood.

¹³² Mungai J. *‘From Simple to Complex’* (1st Edition) (Nairobi: Kenway Publications, 2002), 135
¹³³ CAP 249 Laws of Kenya
¹³⁴ CAP 252 Laws of Kenya
For example in the United Kingdom evidence given at a public inquiry into children’s heart surgery in Bristol showed that it was common place for children’s hearts and other organs to be retained after post-mortem without the parents knowledge or consent. As a result, the Department of Health ordered an inquiry (The Redfern Inquiry) into the Royal Liverpool Children’s Hospital and the results were shocking. A “census” of all organs and tissues retained by pathology services in England showed that:

A total of approximately 54300 organs, body parts, still births or fetuses were held by pathology services at the end of 1999 which had been retained from post-mortems over the period 1970 to 1999.

In Kenya while no census of all organs retained by pathologists has been carried out, we are sure that the results will be even more shocking. However, the knowledge often some years later, that organs or tissue were removed from someone close to them brings profound sorrow to many families especially in developing countries where cultural values demand that the entire body of a dead relative be buried once they die. The family of the late Kenyan minister for Foreign Affairs Robert Ouko, for example, are demanding the return of Ouko’s skull for burial in accordance with Luo customs. It is alleged that the skull was retained by pathologists who were investigating the murder of the late minister.

We have also witnessed certain cases especially in the rural areas where bodies are given to relatives from mortuaries without certain organs and in fact rural

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135 Department of Health, *The removal, retention, and use of human organs and tissue from post-mortem examination, advice from the Chief Medical Officer*, (London: 2001) Page 1
folk are not keen on taking bodies to the morgue for fear that they would be vandalized.

We can only belief that these organs/tissue are retained either after a post-mortem to establish the cause of death (for which no consent is required) or after a hospital's post-mortem (carried out for a variety of reasons, if the next of kin does not object) for example, to confirm a diagnosis where this may have implications for living relatives or to acquire knowledge which may improve treatment for others.

At this point we think it is important to discuss briefly what we mean by human tissue, its source, uses and the concerns that it raises.

1. What is Human Tissue

A tissue is a collection of similar cells that are specialized to perform a particular functions.\textsuperscript{138} They may be of the same type such as nervous tissue, muscular and skeletal tissue or of different types such as connective tissue. Groups of different tissues is organized into organs like the liver, brain and kidneys, which perform specialized functions in the body. The body organs are further supported and covered by other tissue which is familiar to us such as bone, muscle, connective tissue, sheaths and skin.

2. The Sources of Human Tissue

Most commonly, human tissue is removed from the body in the course of diagnosis or treatment. Blood or bone marrow may be drawn for diagnostic examination. Small pieces of tissue may be taken by biopsy for pathological examination and diagnosis and larger amounts of tissue may be removed surgically

during operation for malignant or other disease. Inevitably there may be tissue left over after sampling, surgery or therapy. This surplus is ordinarily discarded and destroyed as clinical waste. However, it may also be made available for scientific research, medical training, scholarship evaluation and review of medical procedures.

An example of left over tissue is the excised foreskin after circumcision which can be used as source of cells. However, there has been some concerns as we will see later in this paper about their disposal. Incidents in which human tissue is not thought to have been handled or disposed off appropriately have given rise to much concern. For example researchers from the University of Nairobi Medical School are reported to have taken foreskins of twenty men from the Oyugis Area of South Nyanza. These foreskins were donated to be used for research on the preference of HIV/AIDS on uncircumcised men to circumcised men. The foreskins were then exported to the United States of America without their consent or knowledge. They are contemplating filing action against the researchers for the return of the foreskins for disposal as cultural beliefs demand. Issues such as this have raised a lot of concern both of law and of professional standards. We recommend that disposal of tissue be handled in ways which show respect, and which is sensitive to cultural beliefs.

Another source of tissue is from autopsy material. Autopsies are carried out to determine the cause of death. Parts of organs and tissue are taken by the pathologist for dissection and study and whole or cut organs may be removed if they illustrate particular processes. Any autopsy examination provides invaluable
opportunities to add to the body of medical knowledge through demonstration 
teaching and training.

The other source of tissue is from cadavers donated for anatomy studies. 
Cadavers may be donated by arrangements made before death, for anatomical 
study and teaching and as such are available for demonstration by dissection. 
Bodies donated for anatomical purposes are fixed and dissected by medical students 
in the course of their training.

The other sources of tissue is through donations by volunteers both during 
life and after death.

3. Uses of Human Tissue

Briefly, once removed, human tissue may serve many beneficial purposes. 
For example in the diagnosis and medical management of individuals and in medical 
research, teaching, training and scholarship. These latter activities contribute to the 
public health and the public good. Research using human tissue may yield products 
which then become widely available for diagnosis or therapy.

4. Concerns – Ethical and Legal

One focus of concern about the medical and scientific uses of human 
tissue in recent years has been the issues raised by the case of Moore-V-Regents of 
the University of California (1990) 793 P2d 478, see also Appendix IV.

Moore had a rare form of Leukaemia, hairy cell leukaemia. The nub of the 
case was that, before Moore was operated on, his physicians were fully aware that

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139 Moore-v-Regents of the University of California (1990) 793 P2d 478, see also Appendix IV
certain of his tissue could be of great potential value to a number of scientific, and commercial efforts. They realized that the patient’s tissue could provide “competitive, commercial and scientific advantages”. But notwithstanding what they knew, the physicians did not inform Moore of the potential value of his tissue. Nor it was alleged, did they seek Moore’s consent to the use of his tissue for these purposes.

The John Moore case was exceptional and typical of the general use of tissue for medical and scientific purposes. It is rare for human tissue removed during medical treatment to be of any interest for medical or scientific research, it is even more unusual for such tissue to be quickly recognized as of tremendous scientific interest and potential commercial value. However, it raises questions of consent and consequently of ownership. This case raised questions about the law, regulations and professional guidelines that might be necessary in such situations.

The person from whom the tissue is removed may also be dead or alive. If the person is alive, the researcher may also be the doctor, with whom the patient should have a close and trusting relationship, but equally the researcher may be some remote and unknown member of the hospital staff or scientist far removed, working for a university (like in the care of the twenty men and their foreskins), a research institute or a commercial enterprise.

The issues which arise are both ethical and legal. For example, there are certain unethical uses of human tissue that are unacceptable in many societies. This includes cannibalism, production of human leather or soap from human tissue. There are also other concerns regarding any rights to the further use of
human tissue once it have been removed. For example what relationship exists between the person who was the source of the tissue and the tissue removed? Does the tissue remain part of the person in any sense, whether symbolically or in some proprietarily sense? Does the person retain any right of control over it or is the consent to removal to be regarded as implying abandonment of the tissue?

Further legal issues may also follow: If the human tissue is abandoned, is it abandoned absolutely or only on terms for example, that it be destroyed? What happens if these terms are not complied with, does any sort of dominion revert to the person from whom the tissue was removed? What happens if explicit permission is needed from the donor and the person is say dead, can permission be sort from a proxy? There are also issues concerning commercialization of tissues and safety concerns especially in the transmission of HIV/AIDS through blood transfusion.

From the above, we can see that the concerns are many and raise a number of questions especially for the doctrine of informed consent which is the subject of this paper.

For the removal of tissue from the living, case law has established that a person must consent to the removal of tissue as we have seen earlier in this paper. In most jurisdictions, case law has established that a living competent adult must consent before the removal of any tissue from his body. The fact that there may be an urgent need for certain tissue cannot legally justify its being taken without consent. The laws commitment to the absolute right to bodily security and integrity
of one person cannot be abandoned in order to save the life of another person. Thus, in a United States case a court refused to order a man to donate compatible bone marrow to his cousin and to save the cousin’s life. Although the court expressed the view that the refusal was morally indefensible;

... to compel the defendant to submit to an intrusion of his body would change every concept and principle upon which our society is founded. To do so would defeat the sanctity of the individual and would impose a rule which would know no limits and one could imagine where the line would be drawn...

English courts have not followed the American way, in the case of the court decided that a woman should be required to undergo a caesarean section despite her objection, to prevent the death of her unborn child. Thus, where a person is legally competent, explicit consent is required, whether the removal of tissue is for therapeutic or non-therapeutic procedures, explicit consent is the rule.

Children between the ages of 16 years and above must, like adults, consent to medical treatment. For children who are under 16 years consent should be sort from the person who has parental responsibility.

Some adults may be legally incompetent to give consent because they are either too disturbed or they may be unconscious. In such cases, tissue may be removed if it is in the patients best interests to do so. The law is not very clear on whether tissue may be removed from such adults for non-therapeutic purposes.

There may be also be situations in developing countries like Kenya where the adult though competent may not be able to give consent because of cultural beliefs and social structure. For example as mentioned earlier in this paper the Giriama and

\[140\] McFall-v-Shimp 10 Pa D & C 3d 90 (1978) Pennsylvania
\[141\] Re S (1992) 4 All ER 671
Kisii people of Kenya are very sensitive to the taking of blood samples from them. This is because they believe that a person’s blood contains their spirit and therefore their being. Removing blood from them is to lose part of them and they may resent giving blood. There is also the belief that the blood may be used for witchcraft. To complicate matters the whole concept of autonomy is alien to them. In such a situation the physician has to obtain consent from the parents or community elders.

In Kenya the removal of tissue from the dead is governed by the *Human Tissue Act* CAP 252. Section 2 provides that:

1. If any person, either in writing at any time or orally in the presence of two or more witnesses during his last illness, has expressed a request that his body or any specified part of his body be used after his death for therapeutic purposes or for purposes of medical education or research, the person lawfully in possession of his body after his death may, unless he has reason to believe that the request was subsequently withdrawn, authorize the removal from the body of any part, as the case may be, the specified part, for use in accordance with the request.

2. Without prejudice to subsection (1) of this section, the person lawfully in possession of the body of a deceased person may authorize the removal of any part from the body for use for the said purposes if, having made such reasonable inquiry as may be practicable, he has no reason to believe –
   
   (a) that the deceased had expressed an objection to his body being so dealt with after his death, and had not withdrawn it; or
   
   (b) that a surviving spouse or any surviving relative of the deceased objects to the body being so dealt with

3. Subject to Section 3 of this Act, the removal and use of a body in accordance with an authority given in pursuance of this section shall be lawful.

This statute does not cover all the circumstances in which tissue might be removed from a dead body. In fact it is a two page statute which addresses certain intended uses of a dead person’s body.
This statute provides for an 'opting' in system whereby permission must be given, based either on the express consent of the deceased or subject to veto of relatives before organs can be taken for such use. Here compliance might be difficult and harvesting of tissue organs may go underground. We propose that the Act be amended to allow harvesting unless there is objection from such procedure in advance. Of course this is likely to raise a lot of debate from moralists but it is worthy thinking about.

The statute does not also deal with the removal of organs from living donors and did not seem to have anticipated developments in medical technology. There is also no other equivalent legislation dealing with the removal of organs from living donors. It is therefore necessary to amend the Human Tissue Act appropriately to provide the legal framework necessary rather than to allow underground practices involving harvesting and trafficking in human tissues to emerge unabated.

The Human Tissue Act CAP 252 Laws of Kenya does not define what tissue is. We all know that an important part of any statute is to define in law what is and is not covered and what the various terms mean. This legislation does not have any definitive part. There is therefore a need to amend the Act to include the definition of words such as tissue, organ, tumours, discarded and diseased tissue.

The Act does not provide for penalties and compensation for persons who may violate its provisions or suffer from such violations. It should be amended to provide for this and this can range from imprisonment, financial penalties and damages.
The Act does not provide for the discarding of tissue or export of tissue. It should provide for this to prevent unscrupulous physicians taking advantage of this lacuna for commercial gain.

It can be seen that from the weakness in the Human Tissue Act CAP 252 and its limited scope, it cannot form the basis of legal action by individuals through the ordinary causes of actions such as battery, assault or malpractice; which may be raised by patients or research persons. It is necessary therefore to revise the Human Tissue Act CAP 252 to provide for a specific legal framework for actions arising from and relating to the removal, use, storage and disposal of human tissue without informed consent.
CHAPTER V

THE APPLICATION OF THE DOCTRINE OF INFORMED CONSENT IN KENYA

Whilst the doctrine of informed consent has been widely accepted in the developed world it is yet to be fully appreciated in developing countries like Kenya. The application of this doctrine has been affected by social and cultural contexts coupled with lack of legislation.

In this chapter we examine how certain social aspects that exist in Kenya affect the application of the doctrine and how the absence of laws on healthcare consent make it almost impossible for patients or research subjects to gain from its ideals.

1. Informed Consent and Socio-Economic Aspects

The standards of informed consent that we have discussed so far assume that society is an homogenous society, a single entity with the same level of healthcare facilities and the same level of education. This of course is not true. Great disparities exist between levels of healthcare that are available, literacy levels which correlate in general quite closely with the degree of socio-economic development of different countries.

Therefore, the standards of informed consent would differ from country to country depending on its level of development. In the western world the values and standards of informed consent as discussed will apply with very little variation.
However, in developing countries the standards will be affected by culture, history, size of population, rate of growth and literacy levels.

Informed consent will also be affected by the availability of technology and other forms of infrastructure that are in place and the availability of healthcare facilities including drugs, and healthcare professionals.

In Kenya for example, you will find that the best medical facilities and healthcare professionals are concentrated in Nairobi and the urban areas whereas rural areas do not have healthcare facilities. At most, one is likely to find one district hospital manned by a clinical officer or one doctor and most often than not such a hospital will be lacking the necessary infrastructure and drugs. The net effect is that choices are limited and this has a negative effect on informed consent. The clinical officer or doctor in a district hospital may also not have enough time to explain to a rural patient the intricacies of a medical procedure and therefore the practice of medicine in such situations is largely paternalistic and is of the community standard.

The other factor that will affect informed consent in developing countries like Kenya is the prevalence of alternative medical systems. One such factor that would influence a rural patient is their understanding and use of traditional methods of healthcare and medical treatment, as well as the nature and level of their familiarity with evidence based modern medicine.

We find this to be necessary because in most societies in developing countries, illness or sickness is ascribed to social, emotional, cosmic or religious causes, for which practitioners of alternative therapies are suitable. This sometimes
leads to patients making choices along established available lines. The first visit being to the traditional medical practitioners or healers and subsequent ones to modern healthcare practitioners or vice versa. This form of decision making is most of the time unwelcome to modern medical practitioners but it is however, a reality that in the long term it is more efficient to address than to ignore because it has a bearing on a patients' autonomy, access to healthcare and choice which is the subject of informed consent.

In Kenya we do not have modern healthcare providers working together with traditional healers because of the way we have been socialized to believe that traditional medicine is evil. The stack reality is that modern medicine as we know it, does not provide all the answers to all situations related to healthcare. In fact, in most developing countries there is a mix of modern medical facilities and indigenous healthcare facilities. This is seen in parts of Africa, Middle East and China. For example, in Burkina Faso there is a combination of modern healthcare and African traditional medicine in providing treatment for people living with AIDS. Here practitioners of modern healthcare work with traditional healthcare practitioners to assess the effects of traditional healthcare on patients.

The effective integration of alternative medical systems has an effect in informed consent in that a physician has to have knowledge of the existence of the two systems and must inform the patient of the existence of alternative systems in order for the patient to make a choice, and therefore be able to give genuine consent.

142 The Health Ministries Meeting “Integrating Traditional Medicine into Health Systems: The example of Burkina Faso” held in Ouagadougou, Burkina Faso 28th August to 2nd September 2000.
There are circumstances where traditional medicine provides the much needed cure for an illness that modern medicine has been found wanting. For example, among the Abagusii community of Nyanza Province of Kenya they will not take a patient to hospital following an injury to the head. Such a patient will be taken to a traditional bonesetter who will operate on the patient using traditional tools and herbs. We have had occasion to witness such an operation and we can attest that they have been very successful.\textsuperscript{143}

The other concern for informed consent in developing countries like Kenya is that the doctrine of informed consent is directed at physicians or modern healthcare professionals. The courts have not found a duty for hospitals or other providers to obtain informed consent, holding that this always flows to the physician.\textsuperscript{144} This has interesting ramifications as healthcare clinics increasingly provide care without direct physician involvement. They cannot be held responsible for their actions.

Interestingly, legislation, common law and medical guidelines have also not extended the duty of informed consent to alternative healers. It is important that legislation in this important area is made so that at least some limited duty is imposed on them to inform patients on the risks of their therapy, and the duty to inform patients that alternative modern medicine exists for their condition where the traditional medicine fails.

We therefore propose that Kenya should develop a protocol that integrates modern healthcare and African traditional medicine for the management of patients. This collaboration is desirable if we are to respect the patient’s autonomy, provide

\textsuperscript{143} Known as “Okobara” (surgery) in the Ekegusii Language
\textsuperscript{144} Ward-v-Lutheran Hosp. & Homes Society of A.M. Inc; 963 P.2d 1031 (Alaska 1998)
choice and therefore provide a meaningful way for patients to give genuine
informed consent.

The other factor that affects informed consent in Kenya is the level of
education. A literate patient is likely to understand the risks of a particular therapy
when they are explained to him or her. An illiterate patient poses a dilemma for the
concept of informed consent. In such a situation the physician will need somebody
to translate the information that he/she wishes to give to the patient in a manner
and language that the patient can understand.

The physician or healthcare provider in developing countries must also take
into account concepts of respect for the family and community as they are equally
important. In fact, in some societies the family and community is more important
than concepts of individual autonomy and rights. In such circumstances it is
necessary to seek family or community consent rather than to seek individual
consent as it is likely to cause conflict within a community.

In summary therefore, the doctrine of informed consent to healthcare as we
know it in the developed world has to be modified to meet local circumstances.
However, to obtain genuine consent health professionals must do their best to
communicate information accurately and in an understandable and appropriate way.
The information provided to patients must be relevant, accurate and sufficient to
enable a genuine choice to be made. The information must be provided in a
language that they can understand, and at their level of comprehension. We note
that the consent forms that are used by most hospitals in Kenya do not in any
meaningful way provide the necessary information or mechanisms that encourage
the process of informed consent. All of them but one are brief and are written in English which limits information flow.\textsuperscript{145}

An awareness of the social and cultural context in which healthcare is conducted is required so that families, communities and individuals can be informed of any aspects of the treatment that may cause them concern. These may include such matters as the amount of blood to be taken, whether they will be examined by physicians of the opposite sex. When obtaining consent it may be necessary to seek consent in the presence of another person, or group, so that the individual feels supported, and more able to ask questions or voice concerns. In other circumstances privacy may be essential, especially where the patient wants to discuss confidential issues such as HIV status.

Lastly, healthcare professionals should respect the limits of an individual's understanding and capacity to deal with difficult information. For example, a patient may have little understanding of the biological processes that take place in their bodies, or have different beliefs about the causes of disease, which make it more difficult to comprehend the information given. However, if all reasonable care is exercised, genuine consent may be obtained.

2. Informed Consent and the Need for Legislation in Kenya

As we have noted, there is no specific statute dealing with informed consent for treatment in Kenya. This has been left largely to common law and the ethos of medical practice. For example, the Medical Practitioners and Dentist Board of Kenya (MPDB) requires that doctors obtain consent where possible before treating any

\textsuperscript{145} Appendix I. It is only Kenyatta National Hospital that has a consent form in both English and Kiswahili
Where it is not possible to obtain consent, any treatment should only be in the patient’s best interest. This code of ethics does not make it mandatory to obtain informed consent and it is largely paternalistic. We discuss below the guidance on biomedical research involving human participants in Kenya. This discussion will show us that there are gaps in the current legal framework that need to be attended to urgently.

3. Consent for Biomedical Research on Humans in Kenya

Kenya has adopted the International Ethical Guidelines for Biomedical Research involving Human Subjects, which gave primacy to the protection of the rights and welfare of participants in research, and particularly those considered to be vulnerable. The legal framework for research came into existence in 1979 following the enactment of the Science and Technology Act 1979. The Act established the National Council for Science and Technology and all Public Research Institutes. The National Council for Science and Technology has been empowered to coordinate all research in Kenya and advise the government on all matters related to research. For research of a biomedical nature to be conducted on humans in Kenya, ethical clearance is mandatory. The Institutional ethical clearance committees do the ethical clearance. The Kenya Medical Research Institute, Kenyatta National Hospital and Eldoret Referral Hospital, Aga Khan Hospital have ethical clearance committees. For a long time it was only the Kenya Medical Research Institute that had research guidelines. Most researchers who wished to do

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146 "The Code of Professional Conduct and Discipline" issued by The Medical Practitioners and Dentists Board (Kenya).
147 Published by WHO/CIOMS in 1993
clinical research were either advised to be affiliated to this institution to have their proposals reviewed or simply did their research without the necessary approval with dire consequences to the participants.

Two cases were reported in the country where it was felt that the necessary clearance had not been obtained from the appropriate authorities. These were the HIV/AIDS research involving The Majengo Sex Workers and The Nyumbani Aids Orphans\textsuperscript{149}. It was reported that clearance had not been obtained from the necessary authorities and genuine consent had not been obtained when the researchers removed blood from the participants for research on the HIV/AIDS Pandemic. The ethical question that was of concern was that for the Majengo Sex Workers adequate information had not been disclosed to the participants regarding the research and that they were patronized, and given inducements to participate. As for the Nyumbani Home Aids Orphans the concern was that blood was obtained from these children without proper consent and because they were vulnerable. We tried to get the protocols of these two cases but we were not able.

Clear standards were clearly lacking and it became necessary for the Council for Science and Technology to set guidelines to fill this lacuna. In 2004 it published the guidelines for the Ethical Conduct of Biomedical Research involving Human subjects in Kenya.\textsuperscript{150} These guidelines borrow very heavily from the WHO/CIOMS guidelines of 1993\textsuperscript{151}. They recommend among other things that:

\begin{quote}
For all biomedical research involving human subjects, the investigator must obtain the informed consent of the prospective subject or in the case of an individual who is not capable of giving informed consent, the proxy consent of a
\end{quote}

\textsuperscript{150} Issued by National Council for Science and Technology; NCST No. 45 (2004).
\textsuperscript{151} "International Ethical Guidelines for Biomedical Research involving Human Subjects" WHO/CIOMS: 1993
properly authorized representative. Informed consent is deemed voluntary if the individual is given the necessary information, he has understood the information, and after considering the information has arrived to a decision to participate without coercion, undue influence, intimidation or inducement.¹⁵²

Looking at these guidelines we find that they are wanting in a number of ways. Firstly, nowhere do they require that a researcher be aware of the social and cultural context in which the research is to be conducted, so that communities and individuals be informed of any aspect of the research that may cause them particular concern. For example in most Kenyan communities, during routine clinical care, information about a diagnosis of a serious disease such as cancer may only be provided to a patient’s family, rather than to the patient. The guidelines require that such information be given to the patient and this may conflict with the wishes of the family or community and even standard medical practice, which is, to withhold the diagnosis of cancer from a patient.

Secondly, the guidelines also make an assumption that the participants in research are literate and generally aware of modern medical practices. The reality is that most of the people are non-literate. The guidelines should have taken this into account to ensure that participants are provided with information about the research in a language that they can understand, and at their level of comprehension. Informing the subject of research, should not be simply a ritual recitation of the contents of the research. Rather, the researcher must convey the information in words that suit the individual’s level of understanding.

Thirdly, the guidelines do not address the issue of some concepts used in research which may be difficult to explain in an understandable manner, particularly in communities with entirely different beliefs about the causes of illness and little familiarity with biomedicine. In such circumstances researchers may need to consult leaders or elders to determine how these concepts can be explained in order to get genuine consent. It may be necessary to incorporate local belief systems into the process of providing information.

Fourthly, the guidelines do not seem to have any sanctions that can be enforced by the Government on researchers who violate or those who do not observe the guidelines and therefore has no teeth. It is necessary therefore that they should be revised to provide for sanctions.

Lastly, it is one thing to have guidance, it is another to interpret and apply it. Guidance is liable to different interpretations in different settings. It is also in the nature of such guidance that it does not seek to be comprehensive enough to cover the wide range of contexts that it is expected to cover. Our current guidelines are just that, general guidelines. It is necessary therefore that the language of the guidelines be reviewed with the view of making them clear and relevant to the circumstances of the people of Kenya.

As for the removal, use, storage and disposal of human tissue we noted in Chapter Four that the piece of legislation that deals with consent is The Human Tissue Act.\footnote{CAP 252 Laws of Kenya (Revised Edition) 1967} Under Section 2 the Act permits the person “lawfully in possession of the body” (usually taken to be a hospital) to authorize the removal of parts of the
body for purposes of medical education or research. This legislation exists to provide a framework within which doctors might be able to more effectively ply their trade and make use of the materials they encounter to better understand the workings of the body. The ability to retain human tissue for analysis and comparison is common practice because of the utility of actually showing the effects of disease or damage upon those tissues, to doctors in training. What has not been common practice is informing the patients or relatives of the extent of retention or ensuring that reasons for the removal and use are properly understood.

The Human Tissue Act 1967 deals with the removal of organs and tissue from a dead person. It requires the person lawfully in possession of the body to ascertain that the “surviving spouse” or any “surviving relative” does not have any objection to such removal.\textsuperscript{154} However, it does not state what the position would be, where tissue has been removed during a person’s lifetime and specific consent has not been sought for a particular use after death, for example to assist in the genetic testing of a relative. The law is currently unclear as to whether such use is permissible. We are of the view that the law be reviewed to make this clear and suggest that where there is no prior consent for the taking and use of organs or tissue, this must actively be sought from those close to the deceased person. This would apply whether the tissue or organ was taken when the person was alive or is to be removed after death. However, again the terms “spouse” and “relative” as used in the Human Tissue Act 1967 are not probably appropriate today. This is because contemporary families often involve more complex relationships than the

\textsuperscript{154} Ibid: Section 2(2)(b)
traditional wife, husband or blood relatives. We recommend the use of the term “next of kin” to describe not only “family” “relatives” and “parents” but also others who may have been close to the deceased person. This will include an unmarried partner or perhaps even a close friend.

As we have seen the Human Tissue Act 1967 does not provide for penalties and compensation in the event of violation of its provisions. It is necessary that it is revised to provide for penalties and compensation.

We have seen that these pieces of legislation and regulations on consent are not sufficient and did not anticipate the development of medical technology and societal scrutiny and therefore have not kept pace with the rapidly advancing scientific and medical developments. There are fundamental ethical and legal questions that beg for answers as we have seen that the current legislation and guidelines do not provide for.

We therefore suggest that the law be amended appropriately to keep pace with these new technological advancement in medicine. However, whatever the motivation, any intervention which is undertaken on a person without the individual having been provided with relevant information to enable him/her to make a choice, is *prima facie* unlawful. As Mason and McCall Smith have put it, “as a general rule, medical treatment, even of a minor nature, should not proceed unless the doctor has first obtained the patients consent.”

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CHAPTER VI

CONCLUSIONS AND RECOMMENDATIONS

In this paper, we have examined the doctrine of informed consent as a legal framework for assessing the duties and responsibilities of those involved in the treatment of patients and those involved in the conduct of research relating to healthcare.

We have noted that the doctrine of informed consent is based on four principles; the duty to alleviate suffering, the duty to show respect for persons, the duty to be sensitive to cultural differences and the duty not to exploit the vulnerable. Rather than formulating a strict prescription of conduct for doctors or biomedical researchers which these principles would require, we have emphasized the critical importance of taking social, cultural and economic contexts into account when applying these principles and have identified the minimum requirements which must be met in all circumstances.

In this report we have argued for the proper approaches to consent, the disclosure standard of consent, the review of the law relating to consent for treatment and the future provision of healthcare that take into account not only the need to protect patients, but also research subjects who are involved in biomedical research. In doing this, it is crucial that the recommendations in this paper are taken as a whole. Thus the flexibility in tailoring procedures for obtaining consent must be accompanied by the development of the law to keep pace with advances in medicine and biomedical research.
We have noted that whereas there is no specific statute in Kenya that sets out the general principles of consent, case law has established that touching a patient without valid consent may constitute the civil or criminal offence of battery. Further, if doctors or researchers fail to obtain proper consent and the patient or research subject subsequently suffers harm as a result of the treatment or research, may be a factor in a claim of negligence against the doctors involved.

We have recognised that advances in medical treatment, scientific research and biotechnology are using human tissue in an ever increasing variety of ways. These uses include the increasing success and consequent demand for, organ and tissue transplantation, the use of human tissue for research on new medicines and the use of human cell lines and genetic material for studying fundamental biological processes. However, society demands general respect for the human body and its parts. It demands that human tissue should not be used at will or abused.

The fundamental ethical duty of one person to another is to respect them. This respect requires of us not to act against a persons wishes. Doctors and researchers therefore must obtain consent from their patients or research subjects before any treatment or research activity. For consent to be genuine, healthcare professionals must do their best to communicate information accurately and in an understandable and appropriate manner. The information provided to patients and research participants must be relevant, accurate and sufficient to enable genuine choice to be made. It must include such matters as the nature and purpose of the treatment or research, the procedures involved, the potential risks and the benefits.
An awareness of the social and cultural context in which the treatment or research is being conducted is necessary so that individuals and communities can be informed of any aspect of the treatment that may cause them particular concern. The process of obtaining consent also needs to be designed to provide opportunities for patients to ask questions about the treatment.

Where there are different alternative medical systems it would be appropriate that doctors and traditional healers inform their patients of the existence of the alternative treatment systems so that the patients can make a choice. It will also be necessary that both modern and traditional medical systems collaborate and work together for the benefit of the patients.

We have seen that medical treatment for which consent has been given may involve the removal of tissue for the purposes of diagnosis or treatment. There may be surplus tissue left over once the diagnosis and treatment have been provided for. This surplus is ordinarily discarded or destroyed. However, such left over tissue, may, be made available for scientific research, medical training and scholarship. We therefore recommend that when a patient consents to medical treatment involving the removal of tissue, they should be informed that the consent is taken to include consent also to the subsequent disposal or storage of the tissue and to any further acceptable use provided that this is regulated by an appropriate ethical and legal framework.

We have also seen that the Human Tissue Act 1967 deals with the removal of organs and tissue from a dead person. It does not give any guidance on the removal of tissue from living persons before they die. We recommend that the Act
be reviewed to provide for this. We recommend that such consent be sought from the next of kin.

We recommend that the Human Tissue Act 1967 be revised to include the provision that those charged with the removal of tissue from donors, should ensure that the explanations given to donors is explicit about the range of intended uses of the tissue and about any risks that the donor may incur either in having the tissue removed or as a consequence of its removal. Only on these conditions can the consent of the donor and hence the procedure be valid.

The Human Tissue Act 1967 does not provide for sanctions and compensation for those who violate its provisions and the victims respectively. We recommend that it be revised to provide for penalties and compensation. The penalties may include; fines, imprisonment and the payment of damages.

From what we have discussed about the doctrine of informed consent it is possible to discern the following principles:

(i) It is the patient who decides whether, when, where and by whom surgery is to be performed.

(ii) For a consent to medical treatment to be valid, it must be informed consent.

(iii) What a patient is told is not to be determined solely by what the practice of the profession is, although knowing that practice can assist the court.

(iv) A doctor must inform a patient of all material risks. What is material is determined by asking the question “what would a reasonable patient want to know?”
(v) Material risks are also those risks that pose a real threat to the patient’s life, health, or comfort.

(vi) A failure by a doctor to fully inform a patient is a matter for the law of negligence.

(vii) The fact that a patient has signed a consent form does not determine the issue. It is for the court to determine if the facts show a fully informed consent.

(viii) The doctor or researcher is subject to the law just as is any other citizen.

(ix) The informed consent law is designed to ensure that certain basic rules of social conduct are obeyed.

(x) It is through the enactment of a proper legal framework on informed consent that the rights of certain vulnerable groups can be protected.

(xi) It is through the law that the right of the patient or research subject to be informed of the nature of his treatment or the research activity can be protected.

(xii) It is through the enactment of a proper healthcare consent law that the medical profession can be obligated to ensure that certain standards of safety are maintained.

(xiii) The Human Tissue Act CAP 252 needs to be reviewed in order to take into account development, in medical research which has resulted in multiple uses of tissue removed from living and dead patients.

Finally and more importantly we propose that a Healthcare Consent Legislation be enacted in Kenya. The purpose of this legislation will provide direction in this important area. Such a legislation will provide rules with respect to consent that forbids a doctor from proceeding with a proposed treatment unless the
doctor is of the opinion that the person is capable of giving consent and has given such consent and if the doctor is of the opinion that the person is incapable of making a decision with respect to the treatment he has obtained consent from the person’s substitute decision maker.

The legislation should provide that no treatment should proceed unless the following elements of consent are met, namely, that the consent relates to the treatment, is informed, given voluntarily and must not be obtained through misrepresentation or fraud.

The legislation should make it mandatory for doctors to provide all relevant information to the patient or research subject regarding the nature of treatment, the expected benefits, the side effects of the treatment, alternatives and the likely consequence of not having the treatment.

The legislation should also make provisions for emergency treatment without consent. This will include circumstances such as when the patient is experiencing severe suffering or indeed is at risk, if treatment is not administered promptly.

The legislation should provide rules with respect to consent to treatment that apply consistently in all settings taking into account local circumstances. It should facilitate admission to hospitals and assistance for persons who are not able to make decisions for themselves.

It should enhance the autonomy of persons for whom treatment is proposed and this includes allowing incapable and vulnerable persons to request that a representative of their choice be appointed for the purpose of making decisions on
their behalf concerning treatment, admission to hospital or any other medical assistance.

The legislation should recognize the role of the family or family members in making decisions when a person lacks capacity to make a decision about a treatment and permit the government or court only as a last resort to make decisions on behalf of persons who are incapable of making treatment decisions or when they have been neglected and or in their best interests.

We recognize therefore, that there is an important and urgent need to enact, consider, clarify and where necessary, strengthen the ethical and legal framework within which healthcare consent, clinical and research uses of human tissue take place. The ethical issues relate directly to the ethical principle of respect for human beings, and that they and their bodies should not be injured and nothing should be done to them and their bodies without their consent.

The limitations of the existing framework both legal and professional regulations in Kenya point to the conclusion that a coherent approach is needed in the enactment of any further regulations. That approach will not necessarily require legislation alone, given the pace of change in biomedical research, a more rapid and flexible approach to regulation may be preferable. But the need to clarify the law is important in so far as uncertainty may impede legitimate treatment, teaching, study or research or even at worst, may encourage illegitimate actions and illegitimate uses of human tissue.

We believe if the above recommendations are given statutory footing they will lead to good professional medical practice.
SELECTED BIBLIOGRAPHY


10. Medical Practitioners and Dentist Board (K) "The Code of Professional Conduct and Discipline" (5th Edition), MPDB: Circular No. 4/79


A patient has a legal right to grant or withhold consent to examination or treatment. Patients should be given sufficient information, in any way they can understand, about the proposed treatment and the possible alternatives, allowing the patients to decide whether they will agree to the treatment. The patient's consent to treatment must be recorded on this form overleaf.

### PATIENT DETAILS

<table>
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<th>Surname:</th>
<th>Other Names:</th>
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<tr>
<td>Registration No.:</td>
<td>Ward:</td>
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<td>Age:</td>
<td>Male</td>
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**Healthcare Professional** shall mean consultant, doctor, surgeon, dentist, therapist or counselor as appropriate.

**TYPE OF OPERATION, INVESTIGATION, OR TREATMENT:**

I confirm that I have seen and examined the patient. I have explained the operation, investigation or treatment and such appropriate options as are available. The type of anaesthetic if any (general/local sedation) has been proposed to the patient in terms which in my judgement are suited to the patient. I have explained this either to the patient and/or to one of the parents/guardians of the patient.

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<th>Name of Healthcare Professional</th>
<th>Name of Anaesthetist</th>
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<td>Signature</td>
<td>Signature</td>
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**ADMITTING HEALTHCARE PROFESSIONAL PLEASE NOTE:**

A patient has a legal right to grant or withhold consent to examination or treatment. Patients should be given sufficient information, in any way they can understand, about the proposed treatment and the possible alternatives. Allow the patients to decide whether they will agree to the treatment. The patient's consent to treatment must be recorded on this form overleaf.

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**CONDITIONS UPON WHICH YOU ARE ACCEPTED AS A DAY SURGERY PATIENT**

1. Before your surgery, you must not have anything to eat or drink as advised by the healthcare professional.
2. You must have arranged for a responsible person to collect you from the hospital and look after you for 24 hours after your operation.
3. After your surgery you must not drink alcohol, ride a bicycle, operate machinery, use a cooker, or undertake any other activity potentially dangerous to yourself or others for at least 24 hours. You must not make important decisions, for at least 18 hours, preferably 24 hours after your operation. You must wait until you feel perfectly well again.
4. If you agree to these conditions, complete the consent form overleaf.
# STANDARD CONSENT FORM

**FOR MEDICAL INVESTIGATION, TREATMENT OR OPERATION**

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**To be used for all surgery including organ donation and transplant, MRI scans, invasive investigations and procedures (including endoscopy, biopsy and angiography); physiotherapy procedures involving movements of force to cervical spine and tests for vertebroartery insufficiency; certain forms of drug therapy, e.g. cytotoxic therapy and and therapy involving the use of ionising radiation and any other case where the doctor deems it appropriate.**

In this form "doctor" shall mean consultant doctor or paramedic (e.g. physiotherapist) as appropriate.

**DOCTOR**

This section to be completed by the doctor/paramedic responsible for care - see notes on this reverse

**Type of Operation/Investigation/Treatment**

confirm that I have explained the above operation, investigation or treatment, and such appropriate options as are available, and the type of anaesthetic proposed (general/regional/sedation), if any, to the patient in terms which, in my judgement are suited to the understanding of the patient and/or to one of the parents or guardians of the patient.

**Surgeon’s signature:** .................................................. **Anaesthetist’s Signature:** ..................................................

**Surgeon’s name (please print):** .................................................. **Anaesthetist’s name:** ..................................................

**Date:** .................................................. **Date:** ..................................................

**PATIENT**

This section to be completed by the patient or if under 18 years of age declaration should be completed by parent/guardian.

**Please read this form and the notes overleaf very carefully**

If there is anything that you do not understand about the explanation, or if you want more information, you should ask the doctor named above.

**Please check that all the information on the form is correct. If it is, and you understand the explanation, then sign the form**

**DECLARATION**

I am the patient/parent/guardian (delete as necessary)

I agree to what is proposed which has been explained to me by the doctor named on this form and to the use of the type of anaesthetic that I have been told about.

I understand that any procedures in addition to the investigation or treatment described on this form will only be carried out if necessary and in my best interest/the best interests of the patient and can be justified for medical reasons.

I have told the Doctor about any additional procedures I would not wish to be carried out straight away without my first having the opportunity to consider them.

**Signature:** .................................................. **Date:** ..................................................

**Name (print):** .................................................. **Date:** ..................................................

**Address (if not patient):** ..................................................
CONSENT FOR AN OPERATION

CONSENT BY PATIENT

_________________________________, hereby consent to undergo the operation of _______________________, the nature, purpose and risks of which have been explained to me by Dr/Mr. _______________________. I confirm that I understand the risks of this procedure as well as the risks associated with anaesthesia.

I also consent to such further or alternative operative measures as may be found necessary during the course of the operation and to the administration of a general, local, or other anaesthetic for any of these purposes.

No assurance has been given to me that the operation will be performed by any particular surgeon.

Date ________________________ Signed ________________________

CONSENT BY RELATIVE

_________________________________, the _______ of the above named _______________________, hereby also consent to such operation.

Date ________________________ Signed ________________________

CONSENT BY PARENT OR GUARDIAN

Patient's name ________________________ I, ________________________, the parent/guardian of the above named, hereby consent to the submission of my child to the operation of ________________________, the nature, purpose and risks of which have been explained to me by Dr/Mr. _______________________.

I confirm that I understand the risks of this procedure as well as the risks associated with anaesthesia.

I also consent to such further or alternative operative measures as may be found to be necessary during the course of the operation and to the administration of a general, local, or other anaesthetic for any of these purposes.

No assurance has been given to me that the operation will be performed by any particular surgeon.

Date ________________________ Signed ________________________

I confirm that I have explained to the patient/parent/guardian the nature, purpose and risks of this operation in a language understood by the patient.

Date ________________________ Signed ________________________

Medical Practitioner
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<th>Yes /No</th>
<th>Notes</th>
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<tbody>
<tr>
<td>CONSENT SIGNED</td>
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<td>JEWELLERY &amp; CONTACT LENSES REMOVED</td>
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<td>WIG, PINS, DENTURES REMOVED</td>
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<td>PRE-OPERATIVE SHAVE DONE</td>
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<td>BLOOD CROSS-MATCHED &amp; HB DONE</td>
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<td>BLOOD AVAILABLE</td>
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<td>IV DRIPS OR CANULA PRESENT</td>
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<td>X-RAYS TAKEN</td>
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<td>URINALYSIS DONE</td>
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<td>PATIENT FILE PRESENT</td>
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<td>IDENTITY OF PATIENT CONFIRMED</td>
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<tr>
<td>OTHER</td>
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</table>

Checked by: ________________________ (ward nurse)
______________________________ (theatre nurse)
______________________________ (anaesthetist)

Bed No: ___________________________ Name: __________________ Procedure: __________________

Doctor: ___________________________ Date: ___________ Time: ___________
RECOMMENDATION FOR INVOLUNTARY TREATMENT

Recommendation for involuntary treatment of .........................................................

1. .............................................................................................................. Hereby declare that:

   1. I am a registered medical practitioner and am the usual
      Medical Attendant of the said ...........................................................
      For I am a registered medical practitioner approved by the
      Director of Medical Services for the purpose of making
      Recommendations under the Mental Health Act.

   2. I examined the said ........................................ on the .........................
      ........................................19 ... And on the .........................................
      19 ....

   3. I have formed the conclusion stated below on the following
      grounds viz;

      ................................................................................................................

   I further declare that:-

   1. The said ................................................................. (Full Name of Patient)
      (a) is suffering from mental disorder
      (b) is likely to benefit from involuntary admission and
      (c) is for the time being incapable of expressing
         himself/herself as willing or unwilling to receive
         treatment.

   2. It is expedient with a view to the said ....................................................
      (Name of Patient)
      recovery that he should be received in the mental institution for a
      period not exceeding six months.

   Signed ..........................................................

   Medical qualifications .................................

   Accepted/Rejected for official use only ..........................

   Signature of the admitting officer
   ................................................................. 19
CONSENT BY PATIENT / NEXT OF KIN FOR AN OPERATION

I, ................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................. of .................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................

hereby consent to undergo the operation(s) of .................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................

the nature and effect of which have been explained to me by Dr./Mr. .................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................

I also consent to such further or alternative operative measures as may be found to be necessary during the course of the operation and to the administration of a local or other anaesthetic for any of these purposes:

* No assurance has been given to me that the operation will be performed by a particular surgeon.

Date ................................................................................................................................................................................................................................................................................................................. (Signed) .................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................

I confirm that I have explained to the patient the nature and effect of this operation.

Date ................................................................................................................................................................................................................................................................................................................. (Signed) .................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................................

* Delete if not required.
CONSENT FORM

(NAME & SVC No of Patient or Guardian) (address)

Hereby consent to undergo or hereby consent to undergoing (Name of patient)

Operation /Treatment of...

The nature and purpose of which have been explained to me by:

DR/MR.

I also consent to such further or alternative operative measures or treatment as my doctor may find necessary during the course of the operation or treatment and to the administration of general or other anaesthetics for any of these purposes. No assurance has been given to me that the operation /treatment will be performed or administered by any particular practitioner.

Signature: (Patient /Parent/Guardian) Date:

I confirm that I have explained the nature and purpose of this operation/treatment to the person(s) who signed the above form of consent.

Signature: (Medical Practitioner) Date:
APPENDIX II

THE TEN REQUIREMENTS OF THE NUREMBERG CODE

1. 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 made known to him the nature, duration, and purpose of the experiment; and the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and their effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment. It is a personal duty and responsibility, which may not be delegated to another with impunity.

2. The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

4. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

5. No experiment should be conducted where there is a prior reason to believe that death or disabling injury will occur, except perhaps, in those experiments where the experimental physicians also serve as subject.

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

8. The experiment should be conducted by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

9. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

10. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill, and careful judgement required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.
APPENDIX III
DECLARATION OF HELSINKI 1964
World Medical Association Recommendations for Clinical Research

I. BASIC PRINCIPLES
1. Clinical research must conform to the moral and scientific principles that justify medical research, and should be based on laboratory and animal experiments or other scientifically established facts.
2. Clinical research should be conducted only by scientifically qualified persons and under the supervision of a qualified medical man.
3. Clinical research cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
4. Every clinical research project should be preceded by careful assessment of inherent risks in comparison to foreseeable benefits to the subject or to others.
5. Special caution should be exercised by the doctor in performing clinical research in which the personality of the subject is liable to be altered by drugs or experimental procedure.

II. CLINICAL RESEARCH COMBINED WITH PROFESSIONAL CARE
1. In the treatment of the sick person the doctor must be free to use a new therapeutic measure if in his judgment it offers hope of saving life, re-establishing health, or alleviating suffering. If at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has given a full explanation. In case of legal incapacity consent should also be produced form the legal guardian; in case of physical incapacity the permission of the legal guardian replaces that of the patient.
2. The doctor can combine clinical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that clinical research is justified by its therapeutic value for the patient.

III. NONTHERAPEUTIC CLINICAL RESEARCH
1. In the purely scientific application of clinical research carried out on a human being it is the duty of the doctor to remain the protector of the life and health of that person on whom clinical research is being carried out.
2. The nature, the purpose, and the risk of clinical research must be explained to the subject by the doctor.
3. a) Clinical research on a human cannot be undertaken without his free consent, after he has been fully informed, if he is legally incompetent the consent of the legal guardian should be procured.
b) The subject of clinical research should be in such a mental, physical, and legal state as to be able to exercise fully his power of choice.
c) Consent should as a rule be obtained in writing. However, the responsibility for clinical research always remains with the research worker; it never falls on the subject, even after consent is obtained.
4. a) The investigator must respect the right of each individual to safeguard his personal integrity, especially if the subject is in a dependent relationship to the investigator.
b) At any time during the course of clinical research the subject or his guardian should be free to withdraw permission for research to be continued. The investigator of the investigating team should discontinue the research if in his or their judgment it may, if continued, be harmful to the individual.
Source: World Medical Association – Geneva

Table 1 - International guidance for the conduct of research related to healthcare

<table>
<thead>
<tr>
<th>Year</th>
<th>Organisation</th>
<th>Title</th>
</tr>
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<tbody>
<tr>
<td>1947</td>
<td>War crimes tribunal at Nuremberg</td>
<td>Nuremberg Code</td>
</tr>
<tr>
<td>1948</td>
<td>United Nations General Assembly</td>
<td>Universal Declaration of Human Rights</td>
</tr>
<tr>
<td>1964</td>
<td>World Medical Association (WMA)</td>
<td>Declaration of Helsinki (1)</td>
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<td>1975</td>
<td>WMA</td>
<td>Declaration of Helsinki (2) Tokyo</td>
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<td>1983</td>
<td>WMA</td>
<td>Declaration of Helsinki (3) Venice</td>
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<td>1989</td>
<td>WMA</td>
<td>Declaration of Helsinki (4) Hong Kong</td>
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<tr>
<td>1993</td>
<td>CIOMS/WHO</td>
<td>International Ethical Guidelines for Biomedical Research Involving Human Subjects (Under revision in 2001-2)</td>
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<tr>
<td>1995</td>
<td>WHO</td>
<td>Guidelines for Good Clinical Practice for Trials on Pharmaceutical Products</td>
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<td>1996</td>
<td>WMA</td>
<td>Declaration of Helsinki (5) South Africa</td>
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<td>1996</td>
<td>International Conference on Harmonisation (ICH)</td>
<td>Harmonised Tripartite Guideline, Guideline for Good Clinical Practice</td>
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<td>1997</td>
<td>Council of Europe</td>
<td>Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine</td>
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<td>1997</td>
<td>UNESCO</td>
<td>Universal Declaration on the Human Genome and Human Rights</td>
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<td>European Union</td>
<td>Charter of Fundamental Rights of the European Union</td>
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<td>2000</td>
<td>UNAIDS</td>
<td>Ethical Considerations in HIV Preventive Vaccine Research</td>
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<td>2000</td>
<td>WHO</td>
<td>Operational Guidelines for Ethics Committees that Review Biomedical Research</td>
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<td>2000</td>
<td>WMA</td>
<td>Declaration of Helsinki (6) Edinburgh</td>
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TABLE 2: The International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS and WHO, 1993)

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Subject</th>
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<tbody>
<tr>
<td>Guideline 1:</td>
<td>Individual informed consent</td>
</tr>
<tr>
<td>Guideline 2:</td>
<td>Essential information for prospective research subjects</td>
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<tr>
<td>Guideline 3:</td>
<td>Obligations of investigators regarding informed consent</td>
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<tr>
<td>Guideline 4:</td>
<td>Inducement to participate</td>
</tr>
<tr>
<td>Guideline 5:</td>
<td>Research involving children</td>
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<td>Guideline 6:</td>
<td>Research involving persons with mental or behavioural disorders</td>
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<td>Guideline 7:</td>
<td>Research involving prisoners</td>
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<td>Guideline 8:</td>
<td>Research involving subjects in underdeveloped communities</td>
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<tr>
<td>Guideline 9:</td>
<td>Informed consent in epidemiological studies</td>
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<td>Guideline 10:</td>
<td>Equitable distribution of burdens and benefits</td>
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<tr>
<td>Guideline 11:</td>
<td>Selection of pregnant or nursing (breastfeeding) women as Research subjects</td>
</tr>
<tr>
<td>Guideline 12:</td>
<td>Safeguarding confidentially</td>
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<tr>
<td>Guideline 13:</td>
<td>Right of subjects to compensation</td>
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<tr>
<td>Guideline 14:</td>
<td>Constitution and responsibilities of ethical review committees</td>
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<tr>
<td>Guideline 15:</td>
<td>Obligations of sponsoring and host countries</td>
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APPENDIX IV

Moore v Regents of the University of California

1. The judgement of the Supreme Court of California on the preliminary legal issues was given in 1990\(^1\). Panelli J in his judgement summarized the facts as follows:

"Moore first visited UCLA Medical Centre on October 5, 1979, shortly after he learned that he had hairy-cell leukaemia. After hospitalizing Moore and "withdrawing" extensive amounts of blood, bone marrow aspirate, and other bodily substances", Golde confirmed that diagnosis. At this time all defendants, including Golde, were aware that "certain blood products and blood components were of great value in a number of commercial and scientific efforts" and that access to a patient whose blood contained these substances would provide "competitive, commercial and scientific advantages".

On October 8, 1976, Golde recommended that Moore's spleen be removed. Golde informed Moore "that he had reason to fear for his life, and that the proposed splenectomy operation ... was necessary to slow down the progress of his disease." Based upon Golde's representations, Moore signed a written consent form authorizing the splenectomy.

Before the operation, Golde and Quan "formed the intent and made arrangements to obtain portions of (Moore's) spleen following its removal" and to take them to a separate research unit. Golde gave a written instructions to this effect on October 18 and 19, 1976. These research activities "were not intended to have ... any relation to (Moore's) medical...care." However, neither Golde nor Quan informed Moore of their plans to conduct this research or requested his permission. Surgeons at UCLA Medical Centre, whom the complaint does not name as defendants, remove Moore's spleen on October 20, 1976.

Moore returned to the UCLA Medical Centre several times between November 1976 and September 1983. He did so at Golde's direction and based upon representations "that such visits were necessary and required for his health and well-being, and based upon the trust inherent in and by virtue of the physician-patient relationship..." On each of these visits Golde withdrew additional samples of "blood, blood serum, skin, bone marrow aspirate, and sperm". On each occasion Moore traveled to the UCLA Medical Center from his home in Seattle because he had been told that the procedures were to be performed only there and only under Golde's direction.

"In fact, (however), throughout the period of time that (Moore) was under (Golde's) care and treatment, ... the defendants were actively

\(^1\) Moore v Regents of the University of California (1990) P 2d 479
involved in a number of activities which they concealed from (Moore) ... specifically, defendants were conducting research on Moore's cells and planned to "benefit financially and competitively... (by exploiting the cells) and (their) exclusive access to (the cells) by virtue of (Golde's) on-going physician-patient relationship..."

Sometime before August 1979, Golde established a cell line from Moore's T-Lymphocytes. On January 30, 1981, the Regents applied or a patient on the cell line, listing Golde and Quan as investors. "(B)y virtue of an established policy... (the) Regents, and Quan would share in any royalties or profits... arising out of (the) patent." The patent issued on March 20, 1984, naming Golde and Quan as the investors of the cell line and the Regents as the assignee of the patent (US Patent No. 4,438,032 (Mar 20, 1984).

The regent's patent also covers various methods for using the cell line also covers various methods for using the cell line to produce lymphokines. Moore admits in his complaint that "the true clinical potential of each of the lymphokines...(is) difficult to predict, (but)... competing commercial firms in these relevant fields have published reports on biotechnology industry periodicals predicting a potential market of approximately $3.01 Billion Dollars by the year 1990 for a whole range of (such lymphokines)...

With the Regent's assistance, Golde negotiated agreements for commercial development of the cell line and products to be derived from it. Under an agreement with Genetics Institute also agreed to pay Golde and the Regents "at least $330,000 over three years, including a pro-rata share of (Golde's) salary and fringe benefits, in exchange for ... exclusive access to the materials and research performed" on the cell line and products derived from it. On June 4, 1982, Sandoz "was added to the agreement," and compensation payable to Golde and the Regents was increased by $110,000. "(T)hroughout this period, ... Quan spent as much as 70 (percent) of her time working for (the) Regents on research" related to the cell line".

2. Moore initially filed suit in 1984 in the California Superior Court against Golde, Quan, the Regents of the University of California, Sandoz, and Genetics Institute. Moore alleged that he had a cause of action in conversion (wrongful interference with another's property) and for lack of informed consent. The case passed from the Superior Court to the California Court of Appeal and then to the Supreme Court of California. The majority of the Supreme Court decided that Moore had no property rights in cells taken from his body, but remitted for trial the issue of whether the doctors had been in breach of the duty to obtain Moore's informed consent and of the duty of loyalty to the Moore as their patient. The case was subsequently settled out of court.