ACCESSIBILITY OF INFORMED CONSENT PRACTICES IN NIGERIA AND THE POSITION OF HUMAN RIGHTS[1]

'The patient has the right to know, and the physician has the duty to inform'.- Dr. William J Curan

Abstract

Informed consent is a cornerstone of healthcare, rooted in both legal and ethical frameworks. It empowers patients to make autonomous decisions about their bodies and medical treatment(s) as well as fosters trust, respect and patient- centered care. Unfortunately, despite its universal application, this practice is a concern in Nigeria. Physicians in Nigeria have been found to be non-complaint in adopting the practice of informed consent. Many patients are not informed of their diagnosis by their healthcare provider, nor are they allowed to be aware of the medications being administered to them. Possible complications that may arise from anesthesia or surgery is hidden. In most circumstances, consent forms for medical treatments are signed by family members or relatives on behalf of a competent, non-minor patient, without the patient's direct consent. Reports show that 71.4% of healthcare providers do not obtain informed consent while 57.1% do not have access to written information about their treatment. These practices are mostly perpetuated at the primary and secondary levels of healthcare and traceable to the culture and cosmology of the people. This paper explores the extent of the accessibility of informed consent practices in Nigeria as well as its limitations.

Keywords: *Patients, Healthcare, Informed consent, Human rights and Accessibility*

I Introduction

Informed Consent (IC)[2] is a legally enforceable right in Nigeria based on constitutionally recognized and protected rights to bodily integrity/ autonomy, self-determination and the right to privacy.[3] The law regarding medical treatment and health research is that patients cannot be involved in medical treatment or research without Voluntary Informed Consent (VIC).[4] This principle is guided by the Code of Medical Ethics (CME). The Code recognizes that adequate consent be obtained from a patient, his relations (if a minor) or appropriate medical authority before conducting any surgery or medical treatment on a patient – thus an essential element of good medical practice is the recognition by the attending physician or dental surgeon, of the inherent right of the patient to his body.[5] This therefore means that a patient has the right to accept, reject or forgo a given medical option.[6] Nevertheless, although the physician has absolute discretion and authority, free from unnecessary non-medical interference to determine when to give his services and the nature of care to give to a patient under his care but he must accept responsibility for any negligent act or omission for failure to seek consent.[7] Accordingly,

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[2] Informed Consent herein referred to as IC

[3] Constitution of the Federal Republic of Nigeria 1999 (as amended 2011) s 37.

[4] VIC Means Voluntary Informed Consent

[5] R. 19 (a*) CME.*

[6] *Medical and Dental Disciplinary Tribunal (MDDT) v. Okonkwo* (2001) 4 SCN 780.

[7] R.8 (h) *CME.*

the physician is therefore absolved from any liability that might occur in event of the patient's decision to forgo treatment. But the physician is more likely to be held liable for negligent act or omission if he has been found to have failed as an expert in his field to provide information to a patient seeking answers to specific issues relating to the patient's condition or care. This attracts a charge of assault and battery as well as indictment for professional negligence on the part of the physician.[8] Some scholars have argued that informed consent is controversial, reason being that the concept is a "myth, a fiction, unattainable, or a snare to entrap physicians.[9] Others maintain that the concept is alien to African's psyche and cultural setting, and cannot conceivably be sought for from an African patient in every procedure.[10] This problem is attributed not just to poverty, ignorance and illiteracy but also to the country's sociocultural environment.[11] Historically, Nigeria is the most populated country in Africa with a population of about 233,668,528 million people as at 2024.[12] It accounts for almost a fifth of the population of Africa. It has a diverse sociocultural environment, with 250 distinct ethnic groupings and languages. The population is made up of Muslims (50%), Christians (40%), and indigenous religious follower (10%). Four major ethnic groups dominate the Nigerian social, geographic and political environment: the Hausa and Fulani tribes in the North, the Yoruba in the Southwest, and the Igbos (Ibos) in the Southeast. Although, Nigeria is endowed with rich natural resources, mismanagement of resources by the leaders has left the country very poor.[13] The per capita gross domestic product (GDP) is about USD$2537.00 in purchasing power parity, but over 60% of the populations live below the poverty level.[14] The infant mortality rate as at 2019 is 60.662 deaths per 1000 live births and 59.181 deaths per 1000 deaths in 2020, a 2.44% decline from 2019. In 2024, the current infant mortality rate is 53. 674 deaths per 1000 live births, a 1.95% decline from 2023.[15] The average life expectancy is 47 years, and the overall literacy level is 68%. Nigerians are known for their fervent religious worship and religion plays an important role in enforcing ethical precepts.[16] Multiplicity of ethnic groupings is only multiplicity of religious denominations. All parts of the country espouse the tradition of extended family relationship and respect for elders.[17] These diverse economic, social and cultural mixes in Nigeria play significant roles in the patient-physician relationship and influence how informed consent is practiced in Nigeria. Furthermore, it fuels medical paternalism and sustains a culture of submission to authority whether such authority is apparent or real. The consequence of such paternalism being incongruous with the concept of individual autonomy because paternalism according to Beauchamp and Childress, intentionally override a person's preferences of actions by another especially where the person whose actions overrides, justifies it by appeal to the goal of benefitting or of preventing or mitigating harm to the person whose preferences or actions are overridden.[18] The result of this paternalism, which gives way to the trend of unethical practice, has regrettably left Nigerian patients with the mentality of "leaving

[8] Ibid R. 19 &20(e).
[9] OI Irehobhude & O Aniaka, 'Informed Consent' (2005) (1) (3) *Journal of Comparative Health Law & Policy;* 97
[10] Ibid, 98.
[11] ER Ezeome & PA Marshal 'Informed Consent Practices in Nigeria' (2008) (2) (1) *Journal of Bioethics*;1
[12] National Bureau of Statistics, Demographic Statistics Bulletin 2022-2024 <https://www.nigeriastat.gov.ng/pdfuploads/DEMOGR... >.
[13] Ibid, Ezeome and Marshall.
[14] Quartz Africa, Sun 25 June 2018, The Poverty Level in Nigeria: Around 86-9 Million Nigerians are living in extreme poverty< http://www.92.com/Africa.nigerianbias>.
[15] Report from Global Matric. Nigeria Infant Mortality Rate 1950- 2020 < http://www.macrotrends.net>.
[16] Ezeome & Marshal (n11) 3.
[17] Ibid 3.
[18] Irehobhude & Aniaka, (n9) 99.

everything in Gods' hands… the belief that the Lord gives and the Lord takes where consequences arise. Unfortunately, this has left Nigeria in the degenerative and abysmal state of its healthcare system.[19] This paper, explores the historical foundation of informed consent practices and highlights those factors that impede or limit the application of informed consent practices in the country. This paper consists of five (5) parts. Following the introduction in part 1, part 2 explains the meaning and importance of informed consent, part 3 discusses the historical underpinnings of informed consent practices in Nigeria. The 4th part brings to fore the barriers or limitations to accessing medical consent in Nigeria and the last part which is part 5 concludes the paper by discussing briefly the position of human rights on consent in healthcare.

2. Brief Overview of Informed Concept

2.1 Meaning of Informed Consent in Healthcare

In health law and policy, informed consent is a doctrine that requires healthcare practitioners to obtain the consent of their patients upon whom treatment is to be administered or surgery performed before embarking on the treatment or surgical procedure.[20] This is ethical as well as legal, derived from the patient's right to autonomy – the right to decide what is to be done with his body. To buttress the above, the Supreme Court of Canada in the landmark case of *Ciarlaviella v Schacter*,[21] held that bodily integrity embodies a patient's right to decide the type of medical procedures that the individual will accept and the extent to which they will be accepted. The power of bodily integrity permits a patient to accept or reject medical treatment which the patient does not consent to as seen in the Nigerian Case of *Medical and Dental Practitioners Disciplinary Tribunal v. Okonkwo.*[22] This goes to show that the standard of care required in medical cases is that of utmost good faith and the duty is to do no harm – *prenon non micere*.[23] It is akin to the consent that is required by the international human rights instruments on indigenous rights.[24] The consent must be free, prior, and informed. By informed, it means that the healthcare provider must disclose or provide in a clear and concise information about the purpose and nature of treatment or research. The information must include the benefits, risks, potential outcomes and alternatives.[25] Ensure that the individual comprehends the information, either documented or oral. Free implies that consent is not valid if obtained by manipulation or coercion.[26] Consent, if obtained involuntarily, by duress or coercion will result

[19] Ilodigwe MN & Nwali RM, Medical Negligence in Nigeria, U*npublished Seminar Paper (University of Nigeria)* 10 March 2015.

[20] I Iyioha & YAkorede, 'You Give Me Welfare but Take my Freedom: Understanding the Mature Minor's Autonomy in the Face of the Court's Parens Patriae Jurisdiction' (2010) (13) (2) *Quinnipiac University Health Law Journal;* 279 at 283

[21] (I993) 2 SCR 119.

[22](2001) 7NWLR (pt.)

[23] Peter Moffet and Gregory Moor , 'The Standard of Care: Legal History and Definitions; The Bad and Good News'(2011) (3) (1) WJL< http://www.nch.nlm.nih.gov.pmc> accessed 26 July 2024; *Helling v. Carey* 83 Wash. 2d 514, 519P.2d. 981(1974).

[24]FO Esiri, Medical Law and Ethics in Nigeria. (Malt House Publication LTD, 2006); the international understanding of the indigenous participation pre-supposes the existence of asset of group rights belonging to specific people that are considered 'original inhabitants on 'aboriginal' to the territory in which a state is located in contrast to other citizens of their state who are considered foreigners on their territory.

[25] LB Fontana & J Grugel, 'The Politics of Indigenous Participation through Free, Prior, Informed Consent: Reflection from the Bolivian case', (2016) (2) (3) An *International Human Rights Journal*; 77

[26] United Nations Development Group Guidelines on Indigenous Peoples Issues (UN Development Group Publication 2008)13;' Preliminary Working Paper on Free, Prior and Informed Consent of Indigenous Peoples in relation to Development affecting their Land and Natural Resources' Submitted by Antonella Leila Motor and the Tebtebba Foundation, UNODC E/CN/4/Sub.2/AC.4/2004/ 4 *Para* 20.

to an action for battery.[27] That is to say that, for consent to be valid, it must be given voluntarily by a patient who has the legal capacity to give such consent.[28]

2.2 The Importance of Informed Consent.

The Supreme Court of Nigeria recognized the importance of informed consent in medical care in the case of *Medical and Dental Practitioner Disciplinary Tribunal v Okonkwo;*[29] Thus, the patient's consent is paramount… the patient's relationship with a doctor is based on consensus, the choice of an adult patient with a sound mind to refuse informed consent to medical treatment, bearing state intervention through judicial process leaves the practitioner helpless to impose a treatment on the patient. This is the core of informed consent. The recognition of a patient's right to give consent is not unique to Nigeria. The English common law recognized the right of every person to bodily integrity and its protection against invasion by others.[30] Similarly, Cardoso J, in United States case of Mary *Schloendorff v Society of the New York Hospital* [31] stated the capacity to give informed consent thus: "every human being of adult age and sound mind has a right to determine what should be done to his body…." Thus. it is important for a patient to be adequately informed of his medical condition and be given the opportunity to choose whether or not to receive such treatment. However, in making a distinction between consent obtained for clinical practice and consent for medical research. It is important to mention that consent for clinical practice involves medical procedures, treatment or surgery while consent for medical research is for research purposes and equally regulated. The Belmont Report and the Nuremburg Code regulates informed voluntary consent for human research. This research must be explained to the patient involved that the consent obtained is for research and not for therapeutic purposes, so the patient has a right to withdraw at any point in time from such research. [32] However, it is important to mention that the scope and focus of this article is on consent for clinical purpose. Although intermittently consent for medical research will be mentioned as both are synonymous with each other.

2.3 Forms of Informed Consent

There is no statute that defines categories of consent in Nigeria. However, in practice, consent to medical treatment may be express or implied.

2.3.1 **Express Consent**

Consent is said to be express where a patient either by written or oral means agrees to a medical treatment or procedure to be carried out on him. Express consent is important in conditions or procedures which have attendant risks. For instance, surgery which requires administration of anesthetic injection; procedure which involves extensive gynecological examinations; and cases of major diagnostic procedure.[33] In the above-mentioned situations, written consent is preferable. Adequate information and explanation of the procedure must be given by the physician in order for the patient to make an informed decision. Therefore, a witness is required to attest to such consent, the attester could be a family member or members of staff of the hospital depending on the circumstance.

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[27] Battery is the application of force on the person of another- Law of Torts
[28] This refers to a minor who has no legal capacity to give consent to medical treatment
[29] (2001) 7 NWLR (Part711) 79
[30]Mason Mc and Smith C, Law and Medical Ethics (Butterworth Publishers.2006) 340
[31] 105 NE 92, 93 (NY 1914)21
[32]Patricia Imade Gbobo and Mercy Oke-Chinda, An Analysis of the Doctrine of Informed Consent in Nigeria's Health Care Services (2018) (3) (69) *Journal of Law, Policy and Globalization.*16-18
[33] Ibid,17

2.3.2 Implied consent

Implied consent comes to play with the action or demeanor of the patient in agreeing to take part in a procedure or treatment.[34] Implied consent is more common in medical or general practice. Where a patient walks into a hospital, stretches out his hands for a procedure or examination without uttering a word but just action, is a form of implied consent. Implied consent is limited in nature as it applies only to minor procedures. Where invasive procedure or examination is to be carried out on a patient, a written consent must be obtained after a detailed explanation of the importance of such procedure or treatment has been given to a patient. However, in cases where implied consent is in doubt, a verbal consent is imperative.

2.3.3 Extra verbal consent

Extra verbal consent needs to be obtained where implied consent is in doubt especially in cases where sensitive and private parts of the body such as the vagina; breast or genitals are to be examined. Procedures where verbal consent is imperative include, insertion of ureteral catheter Chest x-ray, insertion of intravenous cannular, wound dressing, insertion or removal of drainage tube, examination of genitals, breast or rectum, insertion of Naso gastric tubes. Moreso, informed consent can only be given by a competent adult in the right mental state. In the case of a minor or other persons incapacitated in mind or body, a close relative, guardian in locus parentis may sign on behalf of such patients but the interest of the minor must be paramount.[35] The absence of a statue defining the nature of consent would be addressed on the basis of standard professional practice and not by what the law provides. Therefore, obtaining the consent of a patient is not just a legal requirement but also a standard professional practice.[36] The three key components of consent are linked to ethical issues relating to human subjects which include autonomy, beneficence, and justice. Prior to the Nuremberg trials in 1946 and the horrifying accounts of inhuman experimentation carried out by medical physicians sworn under the Hippocratic Oath to do no harm – *non-maleficence*. The voluntary consent of a patient is absolutely essential, and sufficient knowledge should be provided as well as the comprehension of the elements of the subject matter involved as to enable understanding and enlightened decision making.[37] These elements include the nature, duration, and purpose of the experiment; the method and means by which the surgery is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or challenges which may possibly come from his participation in the experiments.[38] Informed consent was treated under the common law writ of trespass to person while modern informed consent was first invoked in the case of *Salgo v Leland Stanford Jr, University Board of Trustees*[39] in non-experimental health care in the 1957 and was further expounded by the Kansa Supreme Court in *Nathanson v Kline.*[40] Consent is said to be informed when it proceeds voluntarily, without fraud, duress or misrepresentation, from a person who has the capacity to understand and appreciate the nature and consequences of the decision to be made as well as the implication, whatever decision he has made. A patient must receive all necessary information to make relevant decision to either

[34] Gbobo & Oke-Chinda (n 32) 17.
[35] Child Rights Act 2003 Art 3 (1).
[36] AMA, Code of Medical Ethics: Informed Consent & Shared Decision Making <https://www/ama-assn.org.ethics.infor.>...
[37] Irehubude & Aniaka, (n9) 98
[38] GJ Anna MA Godin,' The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation' (Oxford University Press New York 1992).
[39] (1957) 15 Cal App 2d 560, 315 P 26 170
[40] (1960) 186 Kant 393, 350 p 2d 1093

accept or reject a course of action and the onus is on the physician to explain to the patient his rights in this regard to enable him make such decision(s). This duty is on the physician and it is the patient's right. The physician owes the duty to inform the patient in the language he understands because failure to do so, will amount to a disregard of his medical duties toward the patient.[41] In Nigeria, for a patient to be competent to receive medical information, such a patient must have attained the age of 18 years, must not be mentally challenged or unconscious. Any patient below the age of franchise in Nigeria or is certified as mentally impaired or unconscious will be automatically disqualified from making treatment-related decision (s).[42] The reason is because in Nigeria, the competence to make health-related decision is not based on functional assessment of the patient's capacity to understand the nature of the decision to be made but is based on status. Thus, a minor incapable of making health-related decision, can have a next of kin decide on his behalf or by proxy but this view has been overruled by the Supreme Court of Nigeria in the popular case of *Dr. Rom Okekearu v Danjuma Tanko*[43] where a tort of battery was made out against a medical practitioner who amputated the injured finger of a patient without obtaining consent from the patient. The court held: 'I place reliance on the Clerk and Lindsell on tort 15 ed p. 429 '… all that was needed to be proved in this class of battery is, the fact that the doctor failed to obtain consent from the patient before carrying out the operation', it goes further in paragraph 4-9 at page 662 stating that "in all other cases, the patient must be given sufficient information about proposed treatment to enable him give an informed consent." Although Tanko lacked capacity because he was fourteen, years at that time, 'Besides, I cannot see the justification of ignoring him to obtain the consent of his aunt (pw2), the appellant did not tell the trial court why he ignored Tanko, a young man who gave valid evidence as plaintiff. There is also no evidence that Tanko was in a state of comma, a state which would have made it impossible to give consent. A rational human being of fourteen years is capable to give consent.' The court therefore overruled the appellant and awarded damages of ten million naira to the respondent (Tanko) and dismissed the appeal. This case brings to the fore the Mature Minor Rule in medical treatment.[44] Thus, in the US case of *Mary Schloendorff v. Society of New York Hospital*,[45] the plaintiff Mary Schloendorff also known as Mary Gamble – an elocutionist from San Francisco – was admitted to New York hospital to evaluate and treat a stomach disorder. Some weeks into her stay at the hospital, the house physician diagnosed a fibroid tumor. The visiting physician recommended surgery, which Schloendorff adamantly declined. She consented to an examination but not for the surgery. During the procedure, under anesthetic condition, the doctors performed surgery to remove the tumor. Mary thereafter developed gangrene in the left arm, ultimately leading to the amputation of some fingers. She blamed the surgery and filed a suit. The court found for Mary that the operation to which she did not consent constituted medical battery. But the hospital which was nonprofit making was held by the court not liable in the action of its employee, analogizing to the principle of charitable immunity. A patient's right to decide what is best for him is sacrosanct. The physicians' decision of medical opinion of what is best for the patient cannot override that.[46] However, there are exceptions to this rule. This exception occurs with respect to underage children or a minor; an unconscious patient whose next-of-kin may not be immediately ascertained or contacted; and in saving lives

[41] Irehubude & Aniaka (n9).
[42] This view may be different in Canada where under 'the Mature Minor Rule,' which permits a minor who fully comprehends the nature and consequences of the proposed treatment to legally consent to treatment.
[43] (2002) 15 NWLR (pt. 791) 657 SC
[44] Ibid (MMR)
[45] 105 NE 92 (CEAPP 1914)
[46] *Sideway v Board of Governors Bethlem Royal Hospitals, 93 NE (Ct app 1918).*

in an emergency situation. In the under listed circumstances, physicians may initiate treatment without prior informed consent. The physician should also inform the patients surrogate at the earliest opportunity and obtain consent for ongoing treatment in keeping with these guidelines.[47]

3. Historical Underpinnings of Informed Consent Practices

Prior to the late 1950s, there was no firm ground in which commitment to IC could take root. This is to say, that there is no relevant history of the physicians or researchers management of information in their encounter with patients and subjects. The major writings of prominent figures in ancient, medieval and modern medicine contain storehouse information about commitments to disclosure and discussion in medical practice.[48] Beginning with the classic text of ancient medicine, the Hippocratic Corpus, the primary focus of medical ethics became the obligation of physicians to provide medical benefits to patients and to protect them from harm. The purpose of medicine as expressed in the *Hippocratic Oath* was to benefit the sick and keep them from harm and injustice. Throughout the ancient, medieval and modern periods, medical ethics developed predominantly within the profession of medicine. With few exceptions, no serious consideration was given to issues of either consent or self-determination. The proper principles, practices, and virtues of truthfulness in disclosure were occasionally discussed, but the perspective was largely one of maximizing medical benefits through the careful management of medical information. The central concern was how to make disclosures without harming patients by revealing their conditions to them. Outright deception was regularly justified as a morally appropriate means of avoiding such harm. The emphasis on the principle, "first, do no harm" promoted the idea that a healthcare professional is obligated not to make disclosures because to do so would be to risk a harmful outcome. Eighteen and nineteen centuries ushered in Benjamin Rush and John Gregory. These writers are cited for their enlightenment views about disclosure and public education. But neither of them advocated for informed consent practices. Rather, they wanted patients to be educated so they could understand physicians' recommendations and be motivated to comply with treatment. They were not optimistic that patients would form their own opinion and make appropriate medical choices. They advised physicians to yield to (patients) in matters of little consequence, but maintain an inflexible authority over them in matters that are essential to life. Gregory underscored that the physician must be keenly aware of the harm that untimely revelations might cause. Sadly, there is no assertion of the importance of respecting rights of self-determination for patient or obtaining consent for any purpose other than a medically good outcome. Gregory and Rush appreciated the value of information and dialogue from the patients' points of view, but the idea of informed consent was not foreshadowed in their writings. The authors of this paper regard this as an oversight and a serious lapse on their part.

Another remarkable writer is Thomas Percival. Percival's historic medical ethics did not make mention of consent solicitation and respect for decision making. Like previous codes and treaties, Percival did however, struggle with the issue of truth-telling, he believed that the patients right to the truth must yield to the obligation to benefit the patient in cases of conflict, thereby recommending benevolent deception. Percival maintained that:

> "(T) a patient … who makes inquiries which, if faithfully answered, might prove fatal to him, it would be a gross and unfeeling wrong to reveal the truth. His right to it is suspended, and even annihilated; because its beneficial nature being reversed, it would

[47] Irehobude & Aniaka (n 9).
[48] Wandler Micheal. 'The History of Informed Consent Requirement in the United States Federal Policy: Harvard University Library < http://www.mrsharvard.edu/urn-3:Hul.InstReps:dash.current.termsof-use/LAA 2001>.

> be deeply injurious to himself, to his family and to the public. And he has the strongest claim, from the trust reposed in the physician, as well as from the common principles of humanity to be guarded against whatever would be detrimental to him … The only point in issue is whether the practitioner shall sacrifice that delicate sense of veracity, which is so ornamental to, and indeed forms a characteristic excellence of the virtuous man, to this claim of professional justice and social duty.[49]

But Percival's friend Rev. Thomas Gisborne, opposed this, and said; the practices of giving false assertions intended to raise patients hope by lying for the patients' benefit is deceitful. The physician…is invariably bound never to represent the uncertainty or danger as less than he actually believes it to be". In his defense, Percival stated that the idea was neither to lie to the patient nor act improperly in beneficent acts of deception and falsehood rather the objective is to give hope to the dejected or sick patient. Further, the *American Medical Association (AMA)* without modification in *1847* accepted virtually without modification, *Percival paradigm* and recoded it in its *"Code of Medical Ethics 1847"*. AMA's position on the obligation of physicians in regard to truth telling remained same with that of *Percival's*. The code of medical ethics did not include rules of veracity although many codes today contain rules of obtaining an informed consent. However, the major problem today is implementation.

In the nineteenth century there was a notable exception to the consensus that surrounded Percival's recommendations. The first champion of the rights of the patient to information is *Connecticut Physician Worthington Hooker* in opposition to the model of benevolent deception that had reigned from Hippocrates to the AMA. The two best known physicians who championed the patient's rights to information are the Harvard Professor of Medicine *Richard Clarke Cabot* and *Hooker* this is prior to the second half of the twentieth century. *Hooker's* arguments are novel and ingenious but do not amount to a recommendation of informed consent. Hooker was more concerned with "the general effect of deception" on society and on medical institutions. He thought the effect to be disastrous. But in Hookers prescription, no more than in AMAs code is there any recommendation to obtain the permission of patient or to respect autonomy for the sake of autonomy. Hooker's concern was with expediency in disclosure and truth-telling rather than with the promotion of autonomous decision making or informed consent. Although the nineteenth century saw no hint of a rule or practice of informed consent in clinical medicine, consent practices were not entirely absent. Evident existed in surgery records of consent-seeking practices and rudimentary rules of obtaining consent since at least the middle of the nineteenth century. However, the consent obtained does not appear to have been meaningful consent because they had little to do with the patient's right to decide after being accurately informed. Practices of obtaining consent in surgery prior to the 1950s were pragmatic responses to a combination of concerns about medical reputation, malpractices, and practicality in medical institutions. It is important to say that such practices of obtaining permission do not constitute practices of obtaining informed consent, although they did provide modest nineteenth century grounding for the twentieth century concept of informed consent practices. This situation is similar in research involving human subjects. Little evidence exists then, until recently, when requirements of informed consent had a significant hold on the practice of investigators. In the nineteenth century, it was common for research to be conducted on slaves and servants without consent on the part of the subject. By contrast, at the turn of the century, American army surgeon *Walter Reed's,* yellow – fever experiment involved formal procedure for obtaining the consent of potential subjects. Although deficient by contemporary

[49] American Medical Association 1847 "Code of Medical Ethics", in proceedings of the National Medical Conventions, held in New York, May 1846, and in Philadelphia, May 1847.

standards of disclosure and consent, these procedures recognized the right of the individual to refuse or authorize participation in research. The extent to which this principle became engrained in the ethics of research by the mid twentieth century is a matter of controversy. Although, it has been reported that obtaining informed and voluntary consent was essential to the ethics of research and was common place in biomedical investigation. It is unclear that consent seeking on the part of investigator was standard practice. Anectodial evidence suggests that biomedical research often proceeded without consent. By the early 20th century, the legal history of disclosure obligations and rights of self-determination for patients evolved gradually. During this period, judicial decisions came to be and legal precedents set. A few early consent cases were built to eventuate in a legal doctrine. One of the best known and ultimately the most influential of the early cases is *Schlendorff v New York Hospital*[50] decided in 1914. Nevertheless, before the Schlendorffs case, there are three other cases such as Mohr *v. Williams*[51], *Pratt v. Davis*[52] *and Rolater v. Strain*[53]. The first two cases, *Mohr & Pratt* easily evaluated together though occurred in different states, both went before the courts over roughly the same time. The two courts also seemed to influence each other even though *Pratt* went before the lower court later than *Mohr;* the final *Mohr* ruling wound up citing *Pratt's* lower court decision.[54] Both cases came out the same way. They both introduced in American courts the concept that a patient has the right to make her own decisions. These two cases were regarded as the first significant consent cases.[55] In the case of Mohr, Mrs. Mohr consented to operation on her right ear, to remove diseased portion of her ear. She consented after a discussion with her family physician, who was also present during the surgery. Under anesthetized condition, the defendant surgeon discovered that her right ear was not as sick as he had previously thought, but that her left ear had serious problems. The surgeon felt that the plaintiff's left ear and not the right ear to which she consented to for a surgery should be operated upon. So, he performed the procedure on the left ear.[56] On realizing this, Mohr sued the surgeon after the operation further impaired her hearing. She argued that the operation was not consented to by her. That it was wrongful and unlawful. The Supreme Court of Minnesota held that the surgeon should have consulted with the patient and obtained her consent before performing any surgery. A doctor cannot assume that a patient has consented to surgery merely because the patient seeks the doctor's advice about treatment.[57] The court citing *Pratt v. Davis* ruled:

> Under a free government, at least, the free citizen's first and greatest right, which underlies all others is the right to the inviolability of his person, in other words, the right to himself – is the subject of universal acquiescence, and this right necessarily forbids a physician or surgeon, however skilful or eminent, who has been asked to examine, diagnose, advise and prescribe (which are at least necessary first steps to treatment and care) to violate, without permission, the bodily integrity of his patient by a major or capital operation, placing him under an anaesthetic for that purpose and operating upon him without his consent or knowledge.[58]

[50] *Mary Schloendorff v. Society of New York Hospital* 211 N.Y. 125, 129, 105 N.E 92 (1914).
[51] *Mohr v. Williams*, 95 Minn. 261, 104 N.W. 12 (1905).
[52] *Pratt v. Davis*, 224 111.300, 79 N.E. 562 (1906) .
[53] *Rolater v. Strain*, 39 Okla. 572, 137 p. 96. 97 (1913).
[54] *Mohr v. Williams* (n51*)* 96.
[55] Ibid.
[56] Ibid.
[57] Ibid.
[58]*Fortner v. Kech* 273 Mich, 261N.W.762 (1935).

In concretizing the principle of autonomy, the court in the case of *Schloendorff*[59] used rights of self-determination to justify imposing an obligation to obtain a patient's consent. Subsequent cases that followed and relied upon *Schloendorff* implicitly adopted its justifiable rationale. In this way the concept of self-determination in medical care and research came to be the primary rationale or justification for legal requirements that consent be obtained from patients. During the mid-era of the nineteenth century, the traditional duty to obtain consent evolved into a new, explicit duty to disclose certain types of information and then to obtain consent. This development needed a new term; and so informed was added onto 'consent', creating the expression informed consent in the landmark case of *Salgo v. Leland Stanford*[60] The court suggested that the duty to disclose the risks and alternatives of treatment was not a new duty but a logical extension of the already established duty to disclose the treatment's nature and consequences. Nonetheless, *Salgo's* case clearly introduced new elements into the law. What was set out as issues for determination in the case of *Salgo* was not whether consent had been given rather it was whether the patient had been adequately informed to give voluntary informed consent. The court thus created not just the language but the substance of informed consent by invoking the same right of self-determination that had heretofore applied only to a less robust consent requirement. Shortly after the above two cases introduced the duty of informed consent, the Kanasa Supreme court in the case of *Nathanson v. Kline,*[61] marked for the first time that physicians liability was rooted in negligence theory rather than battery.[62] The court established the duty of disclosure as the obligation to disclose and explain to the patient in the language as simple as necessary the nature of the ailment; the nature of the proposed treatment; the probability of success or of alternatives and perhaps the risks of unfortunate results and finally the right to disclose unforeseen conditions within the body.[63] The Kansas court decision in Nathanson's case required essentially the same extensive disclosure of the nature, consequences, risks and alternatives of a proposed procedure – as had *Salgo.* After *Nathanson's case,* battery and negligence appeared virtually identical in their disclosure requirements for informed consent. Following the case of *Kansas* was a stream of articles in the medical literature on the issues of consent authored by lawyer. These articles were written to alert physicians' awareness to both informed consent as a new legal development and to potential malpractice risks. Although the reactions of physicians in this era was not well documented but a handful of empirical studies of informed consent in clinical medicine proves some insight. A study in mid 60s revealed that as a result of the awareness, surgeons refused to participate because the consent forms were not operative and not yet a feature of the practice of surgery at that time. By the late 60's the indifference to consent procedures changed as most physicians appear to have come to recognize both a moral and a legal duty to obtain consent for all procedures and to provide some kind of disclosure to the patients. Additionally, the physician's views about proper consent practices in the late 60's differed remarkably from the consensus of opinion and convention from their views today because report shows that about thirty (30%) percent of physician surveyed, thought it ethically proper while half of the physicians surveyed thought it medically proper for a physician to perform a mastectomy[64] with no authorization from the patient other than her signature on the blanket consent form required for hospital admission, more than half

[59] *Schloendorff (*n 50).
[60] *Salgo v. Leland Stanford,* Jr. *University Board of Trustees* (1957) 317 p. 2d 170.
[61] *Nathanson v. Kline* (1960)186 Kan. 393, 350 p. 2d 1093.
[62] RR Faden & TL Beauchamp, 'History and Theory of Informed Consent' (2008) < https://booksgoggle.com.ng>.
[63] *Nathanson* (n 61) *88.*
[64] Mastectomy is the operation of removing the breast or mamma.

the physicians thought that it was ethically appropriate for a physician not to tell a cancer patient that she had been enrolled in a double blind clinical trial of an experimental – cancer drug.[65] By the 70's as a result of numerous or voluminous commentary in the medical literature, many physicians became more aware and cautious about informed consent. Empirical studies conducted at that time showed that at least there was enough documentable consent in such areas as surgery, organ donation and transplantation, and angiography to warrant empirical investigation.[66] Also during this period, the use of specific consent form gained acceptance although was not yet universally acceptable and in use. One of the remarkable negative fears expressed by the physicians at this period was that if patients' condition were to be voiced open to the patients, patients who needed surgery may reject surgery. But all these began to change by the late 1970, with the ascendancy of an interdisciplinary approach to medical ethics. Gradually, informed consent became a moral as well as a legal issue.[67] Prior to World War II, research ethics was not influential; however, one thing that unquestionably influenced thought about informed consent was the *Nuremberg trails.* The *Nuremberg military tribunals* unambiguously condemned the sinister political motivation of Nazi experiments in their review of "crimes against humanity". This code consists of a list of ten principles. One of the codes stipulates that the primary consideration in research is voluntary consent, an essential element under the code.[68] By 1960's the Nuremberg code served as a model for many professional and governmental codes. Several incidents involving consent violations subsequently moved the discussion of post-Nuremberg problems into the public arena and there was a rich and complex interplay of influences on research ethics, scholarly publications, journalism, public outrage, and case laws. The first significant case that arose in the United States during this period where certain patients without cancer were involved and needed to supply answer to whether a decline in the body's capacity to reject cancer transplants was caused by the cancer or by debilitation.[69] Some of these patients were informed orally that they were involved in the experiments but it was not disclosed to them that they were being given injections of cancer cells. No written consent was given and some subjects (minors) incompetent to give consent were involved. The Board of Regents of the State University of New York later censored Southam and Mandel for their role in the research and found them guilty of fraud, deceit and unprofessional conduct.[70] In that case, three doctors at the hospital injected live cancer cells into twenty-two chronically ill and debilitated patients. The doctors had obtained the permission of the hospital's medical director, but they did not obtain consent from any of the patients involved, even though the research was completely non-therapeutic. Some patients were informed that they were involved in the experiment but none was notified that they were receiving cancer cells. Likewise, none of the patients were notified that the test was unrelated to their usual therapeutic treatment.[71] Many of the Jewish Chronic Disease Hospital (JCDH) expressed concern about this cancer study of which William Hyman was one, they filed a suit to force the hospital to disclose these records.

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[65] Wandler (n 46) 98.

[66] Encyclopedia.com, History of Informed Consent < https://www.encyclopedia.com/science/encyclopedias-almanacs-transcripts-and-maps/informedconsent-i-history-informed >.

[67] Ibid.

[68] The Nuremberg Code was formulated in 1950 and 1960; Wandler M, the History of the Informed Consent Requirements in United States Federal Policy, 2001(1)(3) *Harvard Community Journal.*

[69] *Hyman v. Jewish Chronic Disease Hospital* 206 N. E 2d 338 (1965); Jones James H. '. Bad Blood. The Tuskegee Syphilis Experiment' (New York, Free Press) 93

[70] American Medical Association 1847 "Code of Medical Ethics", in proceedings of the National Medical Conventions, held in New York, May 1846, and in Philadelphia, May 1847.

[71] *Hyman* (n 69).

Hyman an attorney was concerned about both the abuse of the patients and the hospital's potential liability to have given experimental injections without consent.[72] It was revealed that the investigators had not presented the study to the hospital research committee and the subjects attending doctors have not been consulted before their patients received the injections, the Board of Regents' Disciplinary Committee held:

> A patient has the right to know he is being asked to volunteer and to refuse to participate in an experiment for any reason, intelligent or otherwise, well-informed or prejudiced. A physician has no right to withhold from a prospective volunteer any fact which he knows may influence the decision… There is evidenced in the record in this proceeding an attitude on the part of some physicians than they can go ahead and do anything which they conclude is good for the patient, and that the patient's consent is an empty formality with this we cannot agree[73].

With this decision, the Board of Regents placed great importance on obtaining subject's informed consent, regardless of the degree of harm or possible therapeutic benefits to the patients.[74] Several years later, a significant case involving consent violation emerged in the United States at Willow Brook State School an institution for "mentally defective" children in Staten Island, New York. This took place by mid-1950. Saul Krugman and his associates began series of experiments to develop an effective prophylactic agent for injections hepatitis. They deliberately injected newly admitted patients with isolated strains of the virus based on parental consents obtained under controversial circumstances that is manipulative. The lack of voluntary informed consent leads to the closure of the Krugman's research unit. The most notorious case of prolonged and knowing violation of subjects' rights in the United States was a much longer more egregious study which captured the states attention. Since the early 1930s, the United States Public Health (USPH) had been conducting a study on the effect of untreated syphilis on African American Males in Alabama. It was said to be designed as one of the first syphilis control demonstrations in the state. The purpose stated by the Tuskegee Syphilis Study was to compare the health and longevity of an untreated syphilis population with a non-syphilitic but otherwise similar population. The subjects knew neither the name nor the nature of their disease. The PHS doctor shockingly failed to obtain consent or informed their subjects about the circumstances of the study. Rather the subjects were only told that they were being treated for "bad blood", a term which was never defined for them and these patients – local African Americans males associated it to a host of unrelated ailments. The white physicians, in addition informed the patients that certain painful research procedures, such as spinal taps, were "Special free treatments" for the ailment, a clear lie on the doctor's part. The doctors clearly manipulated the subjects, relying on the fact that the subjects would trust the doctor's statements and opinion.[75] This study continued uninterrupted and without challenge between 1932 till 1970. In 1972 reporter *Jean Heller* published a profile of the situation on the first page of the *New York.* With this publication, attention focused on the *Tuskegee Experiment* and the US Department of Health, Education and Welfare (DHEW) appointed an ad hoc advisory Panel to review the study and the department policies and procedures for the protection of human subjects. The panel ruled that the Tuskegee Experiment should be discontinued and that subjects requiring care be given proper treatment. They further judged that the study was "ethically unjustified … One fundamental ethical rule is that a person should not be subjected to avoidable risk of death or

[72]Supra.
[73] The Board of Regents' Disciplinary Committee.
[74] Ibid.
[75] Faden (n60)321.

physical harm unless he freely and intelligently consents. No evidence showed that such consent was had and obtained from the participants of this study".[76] Sadly, the panel found that neither DHEW nor any other government agency had a uniform policy for review of experimental procedures or obtaining subjects' consent. Instead, the investigators in the biomedical profession who were conducting the experiments were the one who regulated research practices.[77] Then the panel decried the current situation and offered procedural and substantive recommendations for safeguarding subjects, the congress created a permanent body to regulate all federally sponsored research on human subjects.[78] By early 1970s, the US government had begun to mobilize efforts to draft a federal policy regulating human experimentation.[79] The Tuskegee Syphilis Experiment served as one reminder that the policy needed to be finalized and implemented as soon as possible to prevent further abuse of human subjects.

The United States did not begin the formulation of policies to protect human research subjects until the 1960's. Although the courts based on the numerous court decisions earlier given and international organization had earlier recognized the importance of offering protection to human research subjects. Its federal policies were slower to develop. The agencies that demonstrated maximum concern to this are Department of Health, Education and Welfare (DHEW) and the Food and Drug Administration (FDA) and the National Institute of Health (NIH), they reacted to problem of unregulated research and proposed their own solutions. Their major concern was about the lack of informed consent to medical research and this shaped the development of the ultimate US policy. The first federal policy on human subjects emerged at the Clinical Center of NIH. The Centre created a strict internal code that dictated specific points needed to obtain the subjects informed consent.[80] This landmark principle of the Clinical Center of NIH represents the first established policy regarding complete regulations for clinical testing of new drugs.[81]Henceforth, research subjects were treated as members of the research team as opposed to the period of 1930-1950. Sadly, other agencies did not adopt the policy of Clinical Center neither did they follow suit in establishing their own policies[82]. Report of Boston university's law – medicine research institute revealed that out of the fifty-two (52) medical departments in the then US only nine had a formal guideline regarding clinical research; only two (2) out of the nine (9) had guidelines that were generally applicable to all research.[83] Most of the investigators expressed dislike for self-regulation by committees and preferred to have all oversight directed to the investigators.[84] Obviously the reactions of the American Investigators toward the protection of human subjects were shown vividly by their little or no need to establish policies that guide research in law and medicine. Although, throughout the 1950s and 1960s, the US federal policymakers willingly allowed investigators the latitude they wanted but the period of 1960s – 1980s the FDA made a remarkable change in the promulgation of the *Drug Amendment Act of 1962.* Formerly the *Kefauver – Harris Bill* made important changes in the central laws governing the ethical drug history.[85] The most important and significant changes made during

[76] Report of the Tuskegee Syphilis Study AD HOC Panel to the Department of Health Education and Welfare, in KATZ Experimentation 948.
[77]Ibid, 949.
[78]Ibid, 950.
[79]Ibid. 952.
[80] Faden; Report of Law – Medicine Institute Study 1960
[81] Wandler (n48) 27.
[82] Ibid.
[83] Faden, (n 80).
[84] Wandler (48) 30.
[85] Ibid, 30.

the period include: the requirements that drugs advertising be more carefully controlled; that drug labeling fully disclose precautions and harmful side effects; that there be proof of therapeutic efficacy for drugs; and that the FDA establish complete regulations for clinical testing of new drugs.[86]

The bill emerged as a result of congressional concern about the use and control of drugs. Although hearings before Senator Estes Kefauver's subcommittee on Antitrust and Monopoly had focused mostly on price regulation and drug costs, it gained extra support after the Thalidomide problem in Europe demonstrated the dangerous side effects of drugs.[87] The drug testing situation spurred Senator Jacob Javits to add a consent requirement, marking the first time such a requirement was included in US legislation.[88] Investigators were therefore mandated to both inform subjects if a drug was experimental and to obtain the subjects consent before beginning any study or treatment. However, there was an exception, that if the investigator felt that it were not feasible or if obtaining consent was in the investigator's professional judgment, contrary to the subject's best interests consent need not be obtained. Javits exception proposed on the floor of the senate sadly is vaguely worded. But, remarkably his effort to propose the bill before the senate lead to establishment of consent requirement from patients and subject. This also established the physician's obligation to obtain consent and helped introduce the first consent requirement into American law.[89] Again the consent requirement provision went largely ignored because the FDA staff were busy enforcing other provisions of the bill and there were no legislative debate on the bill until Dr. Frances Kelsey, Chief of the Investigational Drug Branch, Division of New Drugs published it in a paper arguing that the best – interests exception could be validly invoked in only a few isolated cases, such as dealing with children or in emergency cases. This argument limited the exception and established a much tighter consent requirement.[90] Unfortunately though, the FDA regulation applied only to experimental drugs and devices, but not to all research. There was concern by Director of NIH James Shannon for lack of federal policy governing human research. Thus, Shannon met with the National Advisory Health Council (NAHC) in September 1965, in an effort to convince NAHC to establish formal controls on investigators' independence judgment[91] to regulate research on humans and adopted a resolution to address the moral and ethical issues of clinical research. Be it resolved that the NAHC believes that Public Health Service Support of Clinical research and investigation involving human beings should be provided only if the judgment of the investigator is subject to prior review by his institutional associates. This is to ensure an independent determination of the protection of the rights and welfare of the individual(s) involved. Also for the appropriateness of the methods used to secure informed consent, and of the risk and potential medical benefits of the investigation.[92] With this statement, the NAHC acknowledged the significance of obtaining informed consent. However, it made no mention of the definition of informed consent. What this recommendation established was a firm stand to protect individual research subjects. NAHCs resolution led to an established stand in the history of US that; for institutions to receive research grants, they must obtain prior committee review for the proposed research, and must not rely only on the judgment of the individual investigator; on the part of the independence review, they should include consideration of three key elements; the rights

[86] Ibid.32.
[87] Ibid 34
[88] Ibid.
[89] Ibid.
[90] Ibid.
[91] Ibid.
[92] Faden (n 62) 30.

and welfare of the subjects involved, the appropriateness of the methods used to obtain informed consent; and the risks and potential medical benefits of the investigation.[93]

Through the Institutional Guide to DHEW Policy on Protection of Human Subjects, published in 1971, also known as the "Yellow Book", which contained specific guidelines about institutional review, 'informed consent' was defined as the agreement obtained from a subject or from his authorized representative, to the subjects' participation in an activity[94]. The Yellow Book further listed six components of informed consent; a four explanation of the procedure, a disclosure of alternative procedures; a description of risk and discomforts; a description of benefits; an opportunity to ask questions about the procedures; and an instruction that the subject is free to withdraw consent and terminate participation.[95] The above brought to the fore a regulatory system whereby a review panel composed of both medical and non-medical members monitored investigators to make sure that informed consent was obtained and subjects protected. The effect of DHEW's system include establishing a specific definition of informed consent and seemingly tightened the consent requirements to better protect subjects. To further cushion the hard effect of research on subjects and to protect them, the Congress in 1974 passed the National Research Act. The Act served two purposes, first, it required DHEW to adopt as federal regulation in the NIH guidelines about protecting human subjects.[96] Second it created the National Commission for the Protection of Human Subject of Biomedical and Behavioral Research; whose purpose were to conduct a comprehensive investigation to identify the basic ethical principles underlying research on human and to recommend acceptable guidelines to DHEW; Congress and the President.[97] The National Commission's mandate extended before 1974 – 1978 and culminated into Belmont Report 1979. The Commission based its discussion on the three main ethical principles involving human research; respect for persons; beneficence and justice.[98] Each principle was then tied to a specific policy guideline, with respect for persons applied to informed consent, beneficence applied to risk/benefit assessment while justice applied to the selection of subjects and the distribution of benefits of research.[99] Furthermore, the commission[100] following the above format determined that the principle of respect for persons required some form of consent, to protect individuals' autonomy and personal dignity.[101] They assessed informed consent in terms of three necessary conditions namely information, comprehension and voluntariness.[102] The report adopted the standard of a reasonable volunteer, proposing that the extent of disclosure should be such that a reasonably volunteer could decide whether to participate.[103] The commission also emphasized Institutional Review Boards (IRB). In addition, the commission sponsored a study at the University of Michigan to examine functioning of IRBs; it was revealed that most research institutions were happy with the local IRB system because local IRBs protected the subjects. Also, it was specified that the forms for

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[93] Wandler (n48*)*32.
[*94*] Ibid 32
[95] Ibid.
[96] Ibid 33.
[97] Goldner J.A 'An Overview of Legal Controls on Human Experimentation and the Regulation Implications of Taking Professor Katz Seriously (1993) (38)(1) *Journal of Health law*; 43
[98] Morin K. The Standard of Disclosure in Human Subjects Experimentation, (1998) (19)(4*) Legal – Med Journal*; 57
[99] Ibid.
[100] The National Commission for the Protection of Human Subjects of Biomedical Behavioral Research United States.
[101] Ibid.
[102] Ibid.
[103] Ibid.

informed consent be more clearly modified. In response, the commission put out a well – received separate report on IRBs, discussing how to better craft the IRB system.[104] In 1981, the Commission also helped to shape the new regulations issued by DHHs, this regulation replaced those that had been issued in 1974, dealt with requirements for obtaining informed consent as well as the organization and functions of IRBs. This regulation applied only to research receiving federal funds because behavioral and social scientists wanted to only be regulated by the federal government. The major change from the 1974 regulation is, research that poses little or no harm to subjects was now exempted from institutional review.[105] The regulation equally seems less strict than they could have been. The US government at this stage has not imposed informed consent provisions in all possible areas of research. However, in 1991, there was the extension of the scope of DHHs established in 1981. There was the enactment of 45 CFR. Also, sixteen federal agencies including the FDA, the Department of Defense, and the Department of Energy adopted the DHHs regulations into their individuals' codes dealing with the protection of human subjects.[106]

The Common Federal Policy for the Protection of Human Subjects essentially governs all federal sponsored research, as well as commercially sponsored research that is performed for Pharmaceutical Companies and Medical Device Manufacturers. This uninform research standard require that research be considered by an IRB; it also listed guidelines for IRB organization and performance including the criteria for research approval.[107] There was also a prolonged section that gave detailed general requirements for informed consent; the information is to be provided in the language understandable to the subject. Without a clear language it would be deemed that consent whether oral or written is not informed.[108] In addition, the code defines eight essential elements of informed consent to wit: purpose of the research; duration of participation; procedures to be followed; procedures which are experimental; confidentiality; justice; foreseeable risks and discomforts and reasonably expected benefits. These highly specific requirements clearly delineated the boundaries of informed consent. Till date the code of Medical Ethics 45C F.R.S 46 is still in effect. Although there are other current regulations that provided for ways to protect research subjects. DHH's Office for the protection of Research Risk (OPRR) provides federal regulatory oversight of research facilities. Federally sanctioned IRBs grant studies internal approval and human subjects now give voluntary informed consent.[109] Out of the three, the operative regulatory mechanism is the requirement for authentic, uncoerced informed consent – the oversight of OPRR and the approval of an IRB helps government to check compliance to informed consent practices in the US. Informed consent now forms part of the backbone of the US federal policy, this shows that the US government has finally acknowledged the necessity of monitoring investigation and ensuring that human subjects receive the information they need to give consent. This copious historical background of informed consent brings to fore the beginning of informed consent practices globally.

3.1 Informed Consent practices in Nigeria

International regulation and guidelines for human treatment and research emphasize that physicians and researchers must obtain voluntarily individual based informed consent of

[104] The National Commission, Report and Recommendations: Institutional Review Boards (1979)
[105] Ibid.
[106] Ibid.
[107] Ibid
[108] Committee Report, s14 DHHS Regulations/Code.
[109] *Ibid*.

patients and research participant prior to treatment.[110] Equally many research ethic committees require written informed consent and the use of a consent form, which describes the purpose and procedures of the study and its potential risks and benefits, explains that voluntariness of the treatment or research and that subjects can withdraw at any time; and information about maintaining subject privacy and confidentiality in research and medical treatments[111]. Consent forms and other information provided to participants should be in a language understandable to the patient/participant or to the guardian or parent if the patient/participant is a child.[112] In developing countries like Nigeria, the informed consent doctrine is regarded primarily as emanating from Western notion of individualism as opposed to communalism lifestyle in Nigeria. Noteworthy is that African culture is characterized in terms of other people, the individual does not become conscious only of his own being, his own duties, his privileges and responsibilities towards himself but toward other people. According to Mbiti's Maxim "I am because we are, and since we are, therefore I am''.[113] Therefore the doctrine of informed consent favors self-reliance over interdependence, action over passiveness, rationalism over spirituality and uncertainty and forthrightness over collective harmony.[114] This is in contrast to deep religious and ancestral belief systems prevalent in most African cultures which points to an omnipotent, universalizing and fatalistic view of the world that cannot be easily controlled or influenced by mortal human being.[115] Communal and family member consent has been considered as essential in Nigeria as a result of widespread poverty and ignorance which leads to exploitation of medical patients and research individuals.[116] Unfortunately, the haves are more respected and regarded as knowing better than the have not's. The legitimacy and authority the communal leaders have on the people has been compared to those of Mayors, councilors, school principals or heads whose permission is mandatory before any interactions with people who are supposedly under their care[117]. This impliedly leaves the decisions regarding their subjects for them. In most situations, the intervention of community leaders or family heads as the case may be to obtain the voluntary informed consent of potential research patients/participants is an important step to safeguard and foster the wellbeing of vulnerable research patient/participants. This is because community leader engagement helps create community awareness and involvement of the patients/research participants in the community. Therefore, applying the Western concept of autonomy without adequate consideration for the important role of the community leaders and family heads will be a barrier to the application of informed consent in Nigeria. Given that the principle of voluntary informed consent is putatively rooted in individualistic values (especially rights of autonomy and self-determination) it would not be ethically and culturally feasible to effectively apply the principle in Nigeria. Persons whose culture embraces communitarianism concepts may be at a disadvantage in the benefit of the voluntary informed consent requirement because the principle of autonomy is often projected

[110] Council for International Organization of Medical Sciences (I.O.M.S) International Ethical Guidelines for Biomedical Research Involving Human Subjects, (IOMS; Geneva, Switzerland; (2002)
[111] *Ibid*
[112]. Onvomaha, F. P., Kass N and P. Akwengo P 'The Informed Consent Process in Rural African Setting (2008) (1) (1) <https://www.ncbi.nim.nih.gov/articles)> last accessed 10 August 2024.
[113]Ibid. 28
[114] A. Frimpong Mansoh, C. Chima, 2013.
[115] J S Mbiti, Bible and Theology in African Culture, " (1972) 1 (1) *Journal of Theology for Southern Africa.*
[116] Bhutta, Z.A. 'Beyond Informed Consent: Bridging the Know- Do Gap in Global Health', Health law journal (2) 95)2004.
[117]Onvoamba (n 112) 14.

onto individualism.[118] Arguably, personal autonomy should not be a paramount concern among research participants and patients in medical care. Each country should practice informed consent principles as it suits their social and cultural status. In this regard, informed consent should be considered as a process rather than a singular event if there is need to seek permission from community heads and family heads before performing a surgery or approaching an individual for research then this process should be adopted. In so far as the supposed decision is to the best interest of the patient and aimed at doing no harm.

Similarly, in South Africa and Ghana, the requirement of voluntary informed consent requirement is a requirement under the South African law that a patient must provide informed consent for all medical treatment (diagnosis or therapeutic).[119] A cross-sectional qualitative study conducted in Durham City Hospital South Africa in 2017 showed that one of the major issues affecting the application of VIC is that professional nurses in South Africa are deficient in knowledge of local regulations regarding IC and this causes a barrier to IC.[120] Report has showed that South African patients and research subjects are aware of the right to IC similar to Nigerian patients, but many were vulnerable due to indigence.[121] Unlike Nigerian patients who subject themselves to the discretion of the doctor and the will of the Almighty, South African patient prefers disclosure of all material risks, better communication skills by healthcare workers; and a shift toward informed or shared health care decision making.[122] Until recently, physicians in South Africa considered themselves accountable only to themselves, to their colleague in the medical field and to God Almighty. But this has changed now. In South Africa, the physicians have added accountabilities to their patients, to third parties such as hospitals and to healthcare organizations in South Africa and courts and to medical licensing and regulatory authorities.[123] Maintaining or promoting patients' autonomy is of paramount interest to South Africa physicians as advocated in the case of *Canterbury v. Spence.*[124]

4 Barriers to Informed Consent Practices in Nigeria

Informed consent practices can be influenced by sociocultural and religious factors which significantly affect patient's autonomy, decision -making and healthcare outcomes. Below are some of these factors; patriarchal structure, poverty, respect for autonomy, traditional healing practices, religious teachings, illiteracy, family involvement and inadequate laws.

4.1 Family Involvement

The key object of informed consent is to respect the autonomous person and to act in his interest. This principle may be unattainable in African setting because it is believed "that a person is because others are".[125] Unlike many other cultures outside Western Europe and America,

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[118] Ibid 17.

[119] *Staggbeing v. Elliot (*1912).

[120] S Chima, Understanding and Practice of informed Consent by Professional Nurses in South Africa: An Empirical Study – Brief Report, 2017 Conference paper (https://www.researchgate.net/publications>.

[121] Chima SC "Because I want to be informed, to be part of the Decision Making":Patient Insights on Informed Consent Practices by Healthcare Professions in South Africa 2015, 18, 1, 46

[122] *Ibid*

[123] Ibid

[124] *Canterbury v. Spencer*, 1972 464 F. 2d 772 (D.C. Cir.1972), the court held against Dr. Spence in this case thus; the root premise of the concept, fundamental in American jurisprudence, that'' [e]very human being of adult years and sound mind has a right to determine what should be done with his own body…''. True consent to what happens to one self is the informed exercise of a choice ,and that entails the opportunity to evaluate knowledgeably options available and the risks attendant upon each; *Bowers v.Talmage* 1964, 159 So.2d [Fia Dist. Ct. App1964]

[125] I Menkiti,' Personhood and Rights in African Tradition', < https:// www.doi.or/10.1080/02589346.2017.1339176> accessed 13 August 2024.

Nigerians stress a relational understanding of persons as embodied within their family and society. The classical description of family relationship in Nigeria and even in the entire Africa is communitarianism. In other words, duties engendered by rights and those by the idea of personhood will clash.[126] The extended family system sees it as a duty one owes his brothers, sisters, cousins, uncles, aunts, and so forth to help them when in need. This is not just kindness but an obligation that can only be fulfilled by doing one's very best for the family relations.[127] This is simply summed up with the Igbo adage; *ogbu akuwu ekpokoro nwanne ya ubochi nke ya onye ga ekpokoro ya?* This means literally that if a person does not commit himself to the needs of his brother, he shouldn't expect same from others when in need. The extended family members contribute immensely to the welfare and wellbeing of other relatives. They may even be bestowed with the obligation to the entire wellbeing of a family member, to educate the children of relatives and of course be in charge of decision making when need arises; take them to a health center when sick, pay the bills and even decide the treatment or procedure to be carried out on them without permission from the patient. These obligations though not mandatory but a duty owed to another for the sake of solidarity. Failure to do so attracts reprimands and condemnation by other members of the community or brotherhood. This is a major factor militating against consent because health related decisions are often made within the nuclear family and by any adult extended family member even when the patient has the capacity to give consent.

4.2 Belief in Deities:

There is a strong belief in a supreme being such as *Agbara; Amadioha; Ogwugwu; Egungu; Eredumare* depending on a person's denomination which controls both the living and the dead. This belief constitutes a challenge to the effective practice of informed consent in the health care service delivery in Nigeria. It is believed that deities, predestination affect the life of the people; all these are hinged on customs and traditions of the people. This belief vitiates the purpose of informed consent as the essence of informed consent is to enable a patient take control of their health situation by being involved in decisions relating to their lives rather than submitting their fate to deities and Supreme Being (ancestors). Where a person believes that his illness is caused by his *chi* – goddess of his fate he is unlikely to seek for orthodox care especially where such a person is illiterate and has strong belief in custom and tradition. There is likelihood that, he will submit his fate to his *chi* to heal him at his own time.[128]

4.3 Respect for Elders

In Africa, Nigeria inclusive, the cultural practice of respect for elders is a strong norm. This is a duty of obedience and gratitude that is due not only to ones parents but also to the elders because the young person is dependent on these elders for sustenance, education and protection.[129] Therefore despite the principle of autonomy and self-determination, a young person should not be involved in major decision making when the elders or senior members of the family are present. Therefore, it is regarded as proper for decisions regarding health to be

[126] Ibid.
[127] Ibid.
[128] E Amadi (n)
[129] This respect for elders can be seen in the manner of greetings especially among the Yoruba, children prostrate to greet the elders and in Igbo communities, where the younger children are expected not to call their elders by name but include sister, aunt, uncle or brother when addressing them. This is different from the Western world where the younger ones address the older ones by their names. Though the western world may see this act of young Africans as a shift from the common behavior but it is valuable to all Africans because of its symbolic nature .Being regarded a sign of obedience, respect and gratitude to elders.

directed to parents for the best interest of their children. Consent for teenage health problems, including for such sensitive issues as surgeons can only be made legitimately by the parents or older siblings where the presence of the parents is unavoidable. This is also as a filial duty to their younger ones. In these instances a voluntarily self-made informed consent will be almost impossible.[130]

4.4 Gender Disparity

The cultural environment in Nigeria portrays the male folk as superior to the female. This is a similar behavior in most African countries. Roles and hierarchy within the family is defined by the issue of gender. Women in most Nigerian homes are regarded as subordinate to the man. In fact, she is regarded as a lesser being compared to the man who the head/authority and decision making body in the home. This defined gender role is brought to bear on the patient-physician relationship. In order to carry out treatment or any seizure on a woman, the consent of her husband is required. Where they are unavailable, the consent of any other male elder of her family is required.[131] In many cases, consent for caesarean sections or assisted deliveries are obtained from the husband of the patient instead of from the patient. Similarly, before an abortion or similar operation is to be carried out on a woman, the physicians seek the consent of the husband even when the life of the woman is in danger. This privilege given to the menfolk may manifest injustice and leave the woman with life threatening disease. In an unreported case of Mr. & Mrs. Halimat (real names withheld)[132].Two years after the Parties got married, they separated. The woman developed complications as a result of pregnancy. The husband's permission was needed to operate on her but he vehemently refused to give consent. The doctors refused to operate on the woman because the consent form was not signed by the husband and the woman abandoned to her fate. It took the intervention of her relative to move her from the hospital to a prayer house where she miraculously delivered her child few days after. [133] This is not a normative behaviour in all parts of Nigeria and the defined gender role is not immutable because woman in Nigerian 21st century history especially in the North and Western parts have now been known to be preeminent and lords over their male folks. The increased social and economic pressures on families together with increase in the level of education acquired by the women folk, now make it possible and necessary that women contribute more to not only the economic upkeep of their families but also assume larger roles in decision making within the family.[134] In the southern part of Nigeria, many women take medical decisions without seeking the permission of their husbands; and when they involve husband, it's rather a matter of decision instead of by coercion. But it is important to mention here that there are dynamics of each individual family and this might impede or deter the voluntariness of informed consent decisions.[135] Finally, the practice of women depending on their menfolk for medical decision is more prevalent in rural areas among women who depend on their men folk to finance their health care. This is most applicable in the northern part of Nigeria where Islam is the predominant religion and the level of education is low[136].

[130] Ezeome E R & Marshall P A (supra)
[131] *ibid*
[132] The case was a mediation session in Women and Child Justice Initiative Nigeria (WOCJIN) 2019
[133] Eze Chinasa v Eze Nzubechukwu (WACOL Legal Clinic 15 July 2018) unreported, 2018 (real names withheld)
[134] Ezeome E R & Marshal P A (supra)
[135] *Supra; 7*
[136] *Supra*; 8

4.5 Problem of Health Care financing

The type of health care finance system existing in a nation affects informed consent practices because it influences the level of information disclosed. In the United Kingdom (UK) as opposed to Nigeria, medical care is viewed as a publicly provided good, and choices are constrained by, among other things, the total budget that the government commits to medical services.[137] Also in the US, informed consent laws generally reflect support for market allocation mechanisms and thus tend to expand the possibilities for patient choice through more thorough informed consent requirements but in Nigeria, the government espouses a policy of universal basic minimum health care through the National Health Insurance Scheme (NHIS). The reality is that individuals pay for what they get since the services and materials pledged by the Nigerian government are often not available as a result of paucity of resources.[138] In Nigeria, following extensive consultations with various stakeholders from different sectors of the economy, the National Health Insurance Scheme Decree No. 35 of 1999 of Social Health Insurance (SHI) system of health is a public-private sector partnership a shared responsibility between the people and the government for financing the health system – with the ultimate purpose of achieving Universal Health Coverage (UHC). Sadly, despite being implemented for over thirteen years, the NHIS impact on the health care financing system in Nigeria remains monstrously epileptic and covers merely three (3%) percent of the population.[139] Furthermore, charity organizations also play significant roles in healthcare financing. These constraints to a large extent distort voluntary informed consent by defining the level of disclosures that can be made to patients. More so, a patient cannot agitate for autonomy and decision-making rights when he depends on charity for treatment. Where the extended family plays a major role in financing the patients' health care services, the financer becomes de facto decision maker for the patient.[140] Arguably, this to a large extent underpins voluntariness of informed consent because whoever pays the piper dictates the tune.

4.6 Illiteracy

The level of education and sophistication of a patient affects the level of information disclosure that a physician is likely to give a patient. Physicians confirmed that getting informed consent from uneducated people is difficult and time consuming while those of educated people are much easier. The reason is that uneducated patients were least satisfied with the information provided to them. Study on informed consent on people living with breast cancer in Nigeria revealed that women with less education were more likely to seek their husbands' permission to participate in clinical research.[141] Also low educational level significantly predicted the participant's ability to read the informed consent form.[142] The overriding factor in all influences of informed consent in Nigeria is low level of education. It not only neutralizes the various cultural and social factors it equally bridges the gap between the physician and the patient. It encourages discussion on medical matters, and also puts the physician on guard. If one considers

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[137] Annas G J & Miller F. H, The Empire of Death: How Culture and Economics Affect Informed Consent in the US, the UK; and Japan, (1994) (20)(3*) Journal of Law & Medicine*.

[138] *Ibid.*

[139] Nnamuchi O. & Odinkonigbo JJ & Obuka U B & Agu H, 'Successes and Failures of Social Health Insurance Schemes in Africa – Nigeria versus Ghana and Rwanda: A Comparative Analysis' (2019) (28)(1) *Journal of Health Policy and Law Review: An International Human Rights Journal*; 131-132.

[140] Ezeome E R & Marshall P A (supra)

[141] Use 137 here n make 137 ibid

[142] J Onah, UNESCO Laments the Level of Illiteracy in Nigeria, 2007 Business Day (Lagos, Nigeria) <http://businessdayonline-com/print/508-html>.

that in 2007, over 60 million Nigerians have been estimated to be illiterate.[143] Illiteracy is a far more inhibiting factor on informed consent practices in Nigeria than the other factors mentioned above.

4.7 Poor Economic Status

Informed consent in Nigeria's health care services is hampered by economic challenges experienced by patients. Studies have shown that people with poor economic status are likely to accept and obey instructions without either questioning or insisting for their rights.[144] The poverty level in Nigeria in 2011 was estimated at 35.0% and increased to 38.8% by 2016. Despite Nigeria's middle income status, four (4) out of ten (10) citizens lived below the natural poverty line in 2016[145] By 2018, World Bank reported that almost half the population of Nigerians are living below the international poverty line ($2perday) and unemployment peaked at 23.1%. At present, Nigeria is passing through a pandemic and various interstate lockdown as well as income inequality, insecurity, inflation, ethnic conflicts and political instability which have made it difficult for an average individual to cater for basic needs.[146] Furthermore poverty is associated with crippling factors such as lack of confidence and fear. These challenges have made it difficult for a person to institute a legal action for breach of his right to informed consent. Only improved economic status will reduce the inability of patients to seek redress in court for breach of their right to voluntary informed consent in health related matters in Nigeria.

4.8 Trust

Trust forms an integral part of the relationship between a physician and the patient. The effectiveness and success of any form of medical care is based on the trust a patient bestows on his physician.[147] The issue of the abuse of trust by physician is believed to have given rise to the issue of autonomy in the health care service delivery. It is argued that abuse of trust by physician has had no visible effect on the level of trust placed on physician by patients, in fact, the level remains high.[148] Trust is the total confidence or assurance or feeling of security that the physician will take a decision based on the best interest of the patient. Similarly, the essence of informed consent is to protect the self- determination or autonomy of the patient and remove imbalance or inequality in knowledge between a physician and the patient. As a result of inadequate knowledge, most patients in Nigeria have a high level of trust on their physician to make decisions in their interest without questioning such decision.[149] The level of dependence by patients on their physician limits the effectiveness of informed consent in Nigeria's health care delivery system.

5. Conclusion

In medical practice, there is a fundamental principle that every individual has a right to decide what happens to his or her own body. The position of human rights is that the law has an

[143] J. Onah, *ibid*

[144] O Aniaka, Patient Right and Socio- Cultural Challenges to Informed Consent in Nigeria' www.languageconnections.com/descarges/clinicaltrailsinsouthafrica.pdf Accessed 2 February 2017

[145] Punch Newspaper, 11 Feb 2020 < https://punchng.com. >.

[146] Index Mundi, Nigeria Population below Poverty Line, https://www.indexmundi.com 2019.

[147]DA Axelrod & SD Goold 'Maintaining Trust in the Surgeon- Patient Relationship: Challenges for the Millennium' (2000) 135 Archives of Surgery; 55.

[148] A Mark, F Camacho et al 'Trust in the Medical Profession: Conceptual and Management Issues'(2000) 37(5) Health Services Research 1419.

[149] Emmanuel R and Marshal AP 'Informed Consent Practice in Nigeria' (2009) (9) (3) Developing World Bioethics *Journal of International law;* 133-148.

obligation to protect and respect such right.[150] In other words for a procedure to be carried out on a person, such a person must give consent. The individual also has unfettered right to accept or refuse any treatment. However, the exception to this is in emergency situation or overwhelming interest of the public. Sadly, it is observed that in medical practice in Nigeria, consent to treatment is grossly inadequate because often necessary information is not disclosed to the patient (s).[151] This issue is mostly identified at the primary and secondary level of healthcare. The study confirms that majority of patients utilizing public healthcare systems are vulnerable because they are indigent and lack alternative means of obtaining healthcare services. The study further shows that most patients in Nigeria are denied their rights to informed consent because of factors such as religious belief, poverty, illiteracy and so forth. However, although these patients want to be informed and participate in health-related decision-making process but are limited by these sociocultural and economic factors. It found that there are inconsistencies between the policies and actual practice with patients and physicians differing in content and procedures or methodology of information disclosure. Other socio-cultural factors that further inhibit informed consent practices in Nigeria are poor communication skills by HCWs, language barriers, family heads and ignorance. It is of fundamental importance to further educate patient on their rights. The HCWs are required to be educated on patients' rights and the legal implications of failing to comply with the requirements of medical treatment. Most importantly, there is the need to improve the communication skills between the physician and the patients. This will further enhance patient – physician relationship, to protect patient rights and human dignity. Further research should focus on informed and shared healthcare decision making in order to improve preventive healthcare services. The court is not left out in this gap; the judiciary is expected to do more in this regard by defining the limits of the duty of consent on the physician. The landmark case of Okonkwo has not been able to define this because its full impact on informed consent among physicians in Nigeria has not been realized. Its decision is merely regarded as aligning to religious belief and not the limits of the duty of consent a physician owed a patient. There are laws but its implication is inadequate. Nigerian courts are to align themselves with countries like US and UK where the courts have been able to close the gap of the limits of consent through a plethora of cases.

[150] Imade Gbobo P and Oke-Chinda M , *Ibid;24*
[151] Ibid