Informed Consent in MedicaL Procedure, Human Subject Research and Clinical Trials in Nigeria: Where is the Law ?*[1]

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Abstract

The emergence and reality of Informed consent in medical procedure remains one of the most contested areas in law. There is the principle of informed consent in medical practice which mandated physicians to obtain informed consent for diagnostic and/or therapeutic medical procedures affecting patient and also informed consent in human subjects research. It is a fundamental principle of medical ethics and patient rights which ensures that patients/victims are adequately tutored of the medical implication of a medical decisions affecting their bodies to enable them exercise autonomy over the said medical decisions affecting their bodies. In Nigeria, however, the practice remains fraught with challenges. Patients/victims are often subjected to medical interventions without adequate disclosure of risks or alternatives inherent in the decision they are making. Without adequate disclosure giving an informed consent by a victim is not practicable. This is a reality that undermines the protection offered by constitutional guarantees, statutory provisions such as the National Health Act 2014, and professional guidelines. The question is to what extent is informed consent in medical procedure practicable in Nigeria? To what extent is a disclosure standard that adequately balances medical expertise with patient autonomy adopted to ensure accountability? This study examines whether the principle of informed concept in medical practice in Nigeria is a ruse or reality. The objective is to analyse the role, implication and significance of informed consent in health care delivery, identify lapses and suggest solutions to strengthen enforcement in Nigeria. Nigeria remains the scope of the study while the study adopts a doctrinal approach.

Keywords: Informed Consent, Medical Procedure, Nigeria, Applicability, Research, Ruse or Reality.

1. **Introduction**

Informed consent presupposes a voluntary decision by a competent patient emanating from an informed knowledge to accept or refuse medical treatment/procedure, based on a clear understanding of the risks, benefits, alternatives, and consequences of the medical treatment/procedure. It is a legal, ethical, and professional requirement that ensures patient autonomy and prevents coercion, but often involves a documented conversation between the clinician and patient/victim. It is a process in which a healthcare professional educates a patient about the risks, benefits and alternatives of a given procedure or intervention affecting the patients decision about his/her body. Thus, the key components of informed consent includes but not limited to information disclosure which warrants that the Clinicians must disclose the diagnosis, nature of the procedure, risks, benefits, and alternatives including where there is no treatment available; Voluntary Authorization which demands that the patient must agree without pressure, coercion, or manipulation; Capacity which entails that

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the patient must possess the mental capacity to understand the information, appreciate the consequences, and make a responsible decision; Documentation, in the sense that while informed consent is often a written, signed form, consent can also be verbal or implied by action such as offering an arm for a blood test. The concept of informed consent began to emerge in response to several landmark legal cases, such as the case of *Schloendorff v. Society of New York Hospital*(1914), where the court ruled that every human being of adult years and sound mind has a right to determine what shall be done with his own body. This ruling established the principle that patients must agree to medical procedures. Informed consent goes hand in hand with disclosure. Disclosure, in this context, refers to the obligation of healthcare providers to furnish patients with adequate, truthful, and comprehensible information about their health status, diagnostic findings, treatment options, associated risks, and possible outcomes. According to Onyegbule Kelechi Goodluck (2025), it further extends to a medical practice which essentially entails the rights and duties concerning the exchange of information between patients and healthcare practitioners. This is central to the topic of medical ethics, informed consent and patient autonomy. It has both legal and ethical implications. Whereas legally it creates liability because failure to obtain proper informed consent can lead to lawsuits in medical negligence. Ethically, autonomy honors the patient's right to control their own body. while informed disclosure and honest communication foster trust, transparency, and collaboration between the professional/provider and the patient/victim. The concept of disclosure plays a pivotal role in promoting trust, safeguarding patient autonomy, and ensuring ethical medical practice as Beauchamp and Childress(2009)noted. It also encompasses the patient's right to receive such information in a manner they can understand, in order to make informed decisions about their care. In essence, disclosure forms the bedrock of informed consent and is central to the realization of patient rights in any functional healthcare system.

In Nigeria, the legal and ethical dimensions of disclosure are recognized across various statutory and professional instruments including The Constitution of the Federal Republic of Nigeria (CFRN) 1999 (Fifth Alteration), which guarantees the right to dignity and personal liberty under Sections 34 and 35; the National Health Act (2014), which in Section 23 affirms a patient's right to full disclosure of their health status and treatment options; and the Medical and Dental Practitioners Act, Cap M8(2004) Laws of the Federation of Nigeria 2004 which provides for the regulation of professional conduct through the Medical and Dental Council of Nigeria (MDCN). In addition, policy frameworks such as the Patients' Bill of Rights introduced by the FCCPC reinforce the right of patients to receive comprehensive medical information. Despite these provisions, there remains a significant disconnect between legal expectations and clinical practice. Studies show that many patients in Nigeria are not adequately informed about their diagnoses, treatment risks, or alternative therapies, Okpala(2019). Healthcare providers frequently adopt a paternalistic model of care, selectively disclosing information or omitting crucial details. This reality raises concerns about the legal validity of consent so obtained and the ethical soundness of such clinical practice. One major under-explored but critical aspect of disclosure in Nigeria is the issue of medical error disclosure. In many jurisdictions, including the Unites States of America (US), United Kingdom and Canada, disclosure of medical errors is a legal and ethical imperative

aimed at enhancing accountability and patient safety(WHO 2016). However, Nigeria lacks specific legislation or enforceable guidelines mandating the disclosure of such errors. This legislative vacuum fosters a culture of silence and institutional cover-up, which undermines patient trust and perpetuates unsafe medical practices. There is every need to bridge the legislative gap for a safer medical practice in Nigeria.

2. History of Informed Consent

The history of informed consent in medicine is rooted in a broader evolution of ethical practices and legal standards surrounding patient autonomy. In the early 20th century, medical practice was largely paternalistic, clinicians were making decisions on behalf of patients without necessarily informing them of the details and implications. The concept of informed consent began to emerge in response to several landmark legal cases. According to research (Bazzano et al.(2025), a series of four judicial decisions in the early 20th century laid the foundation for the principle of patient autonomy. These legal decisions began in 1905, with the cases of *Mohr v Williams (1905)* and *Pratt v Davis(1905).* Subsequently, two additional cases *Rolater v Strain(1913)* and the 1914 case of *Schloendorff v Society of New York Hospital(1914)* joined the list. where the court ruled that every human being of adult years and sound mind has a right to determine what shall be done with his own body. This ruling established the principle that patients must agree to medical procedures.

Mrs Anna Mohr, the plaintiff, in the case of *Mohr v Williams(1905),* consented to an operation on her right ear; however, as soon as she was anesthetized, the defendant physician changed the plan of surgery from the right ear to the left after determining that the right ear was not as severely affected by disease as had been expected. Mrs Mohr's hearing was further impaired by the operation, and she sued the surgeon for assault and battery in changing the laterality of the operation without her consent. The Supreme Court of Minnesota agreed that the surgeon should have obtained the patient's consent before performing surgery on the opposite ear.

Similarly, in the case of *Pratt v Davis(1905),*a 1905 Illinois appellate decision, the plaintiff, Mrs Parmelia Davis, had filed suit against her surgeon for battery after he performed a hysterectomy without her consent. The physician had obtained consent for an earlier operation but admitted to failing to obtain consent for the second procedure and not disclosing the fact that he intended to perform a hysterectomy to treat Mrs Davis's epileptic seizures. The surgeon, Dr Edwin Pratt, acknowledged intentionally misleading the plaintiff as to the purpose of the operation, claiming that because Mrs Davis suffered from epilepsy, she was not competent to give her consent or to deliberate intelligently about her situation. In its decision in favor of Mrs Davis, the appellate court stated,

> …under a free government at least, the citizen's first and greatest right, which underlies all others is the right to the inviolability of his person, in other words, his right to himself is the subject of universal acquiescence, and this right necessarily forbids a physician or surgeon, however skillful or eminent, who has been asked to examine, diagnose, advise and prescribe (which are

at least the necessary first steps in treatment and care) to violate without permission the bodily integrity of his patient.

The case of *Rolater v Strain(1913)*, rather extended the findings of the legal decisions in *Mohr v Pratt* to similar situations in which surgeons performed procedures that the patient had explicitly controverted. In *Rolater*, the plaintiff sued her surgeon for removing a bone from her foot during an operation that was ostensibly to incise and drain an infection. While the surgeon had obtained consent to perform the procedure to drain an infection, the patient had expressly stated the wish that the surgeon not remove the bones of the foot during surgery, so that the removal constituted a trespass to her person and resulted in the charges of assault and battery. In contrast to the ruling in *Mohr v Pratt*, in the *Rolater* case, the surgeon had obtained the patient's consent before the surgical procedure and performed the surgery on the proper foot. Nevertheless, the Supreme Court of Oklahoma held that the principles of the earlier cases of *Mohr v Pratt*, and *Pratt v Davis* were applicable because the surgeon had not performed the procedure in the manner agreed upon between the physician and patient.

The 1914 case of *Schloendorff v Society of New York Hospital(1914)* was the final landmark case that legally established the principle of patient autonomy. The plaintiff, Mary Schloendorff, explicitly stated her wish not to undergo surgery yet was subjected to hysterectomy to remove a fibroid tumor without her consent. In the ruling, Judge Benjamin Cardozo wrote in *Schloendorff v Society of New York Hospital(1914)* that 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 patient's consent commits an assault, for which he is liable in damages.

The legal decision in *Salgo v Leland Stanford Jr University Board of Trustees(1957)* brought the principle of informed consent to the front burner. It was the said decision of the court that first identified and focused attention on the need to provide the patient with information about the potential benefits and risks of any medical procedure. Before then, the principle of informed consent was obscure and not legally binding until the term was first publicly recorded in the court documents for the 1957 *Salgo's* case. In that case, the plaintiff, Mr Martin Salgo, had arteriosclerosis of the aorta and underwent a translumbar procedure to evaluate its extent. During the procedure, a contrast agent was injected into his aorta to identify blockages, and the procedure resulted in permanent paralysis of his lower limbs. Mr Salgo sued the university medical center and its chief surgeon for lack of disclosure of this potential risk. In a California appellate court decision, the court directed that each physician must exercise practical insight in completely divulging potential procedural hazards and that physicians are liable for failing to disclose information that a patient would need to make an informed decision regarding medical procedures. These cases form the legal framework for the principle of informed consent, as well as the legal framework for the duty of physicians to obtain informed consent for diagnostic and/or therapeutic medical procedures affecting patients.

However, the concept of informed consent in human subjects research began to emerge in parallel as a consequence of the investigation of Nazi war crimes at the end of World War II. The trial of 23 physicians and bureaucrats charged with crimes against humanity and war crimes for medical experiments conducted on concentration camp inmates concluded in Nuremberg, Germany began it all and opened many legal minds to this(1947 Nuremberg).The International Military Tribunal, set forth a series of 10 basic rules for the conduct of human experiments that has become known as the Nuremberg Code. The tribunal laid down these rules on permissible medical experiment. The great weight of the evidence before the Tribunal was to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. The Tribunal agreed, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:

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 so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should 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 the 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 an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects.

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 only 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 judgment required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject"(United States Holocaust Memorial Museum 1949).

The Key principles of the Nuremberg Code include voluntary consent, scientific validity, safety and risk, freedom of withdrawal, qualified personnel. By Voluntary Consent, the subject must have legal capacity, be free from coercion, and understand the risks. Under scientific validity, the researcher must ensure that experiments must be based on prior animal testing, aim for fruitful results for society, and not be random or unnecessary. Procedures must avoid unnecessary suffering of the victim, and risks should never exceed the humanitarian importance of the study. Furthermore, the subject must be able to end the experiment at any time and it is only qualified scientists that should conduct research, with the ability to stop it if injury seems likely. Though not a legally binding law in itself, but the Nuremberg Code has heavily influenced international ethical standards. It was created specifically to prevent future atrocities similar to those committed in Nazi concentration camps,(1947) The "Doctors Trial"-(USA v. Karl Brandt et al.). The Nuremberg Code seems to be the first explicit attempt to regulate the ethical conduct of research experiments with human subjects and is notable for the emphasis it places on voluntary consent and permissible medical experiments.

3. Progressive Development of Informed Consent in Various Jurisdictions

The Nuremberg Code has continued to influence various jurisdictions in adopting the principle of informed concept in medical practice and procedure. *Natanson v Kline* (1960) and *Canterbury v Spence(1972)* form good examples. Also, the Canadian case of *Reibl v Hughes(1980),* the South African case of *Castell v De Greef(1994), Sidaway v Bethlem Royal Hospital(1985)* in United Kingdom. However, in *Montgomery v Lanarkshire Health Board(2015)* the Supreme Court embraced a patient-centered approach, mandating that doctors share risks and alternatives based on a reasonable patient's perspective. Also instructive are the India case of *Samira Kohli v Dr. Manchanda(Law No.2002),* the France case of *Loi Kouchner* which legally enshrined the right to information and consent for patients.

In Nigeria, the *locus classicus* case is the *Medical and Dental Practitioners Disciplinary Tribunal v Okonkwo*(2001) in which the Supreme Court upheld a Jehovah's Witness's right to refuse a blood transfusion. However, it is our opinion that the refusal of blood transfusion was based on religious belief and may not be categorised as informed consent. This landmark case highlights Nigeria's formal recognition of informed consent. However, enforcement remains a challenge. The journey of informed consent reveals a significant

transformation from a doctor-centric model to one that prioritizes patient autonomy. Today, informed consent is firmly anchored in human rights law. In Nigeria, the National Health Act 2014 and the Okonkwo case have aligned Nigerian law with international benchmarks. The emphasis on shared decision-making underscores that consent is a dialogue, not merely a signature, and a cornerstone of ethical medical practice. Since the 2010s, informed consent has been evolving towards shared decision-making (SDM): a collaborative model where doctors and patients engage in discussions about options, risks, and individual values. Thus, legal frameworks now stipulate that consent requires patient capacity, voluntariness, understanding of information, and documented agreement; Consent is an ongoing process, not a one-time event and Patients have the right to refuse treatment, even if it could be life-saving.

4. Legal Frameworks for Informed Consent in Nigeria

Domestic statutes in Nigeria provide the foundational legal basis for informed consent, rooted in constitutional protections and specific health legislation. These laws emphasize patient rights while balancing them with public health needs.

(a) The Constitution of the Federal Republic of Nigeria, 1999 (5th Alteration)

The Constitution of the Federal Republic of Nigeria 1999 (fifth Alteration) serves as the grundnorm, establishing fundamental human rights that implicitly and explicitly support the doctrine of informed consent in medical procedures. Though the constitution does not explicitly mention "informed consent," several provisions protect bodily integrity, dignity, privacy, and health, which courts have interpreted to encompass the right to autonomous decision-making in healthcare. Such provisions are contained in the following sections of the Constitutions: Section 33(1) guarantees the right to life; Section 34(1) guarantees respect for the dignity of the human person; Section 35(1) protects personal liberty; Section 37 safeguards privacy; Section 38(1) on freedom of thought, conscience, and religion; Section 39(1) safeguards freedom of expression; Section 42(1) prohibits discrimination; Section 45(1) allows limitations on rights for public health. In Chapter II of the Constitution, Section 17(3)(c) mandates that the health, safety and welfare of all persons in employment are safeguarded, while Section 17(3)(d) requires “adequate medical and health facilities for all persons. These directive principles, though non-justiciable, guide policy and reinforce health as a right, implying informed consent as part of quality care.

The Fifth Alteration (2023) did not directly amend these provisions but strengthened judicial independence. For instance Section 233 of the Constitution aids enforcement of rights in medical cases. Nigerian courts, have interpreted these sections to affirm informed consent as a constitutional imperative, holding that patients’ rights to dignity and liberty preclude non-consensual treatments except in life-saving emergencies. This is to ensure that informed consent is not merely ethical but a fundamental right. Nonetheless, there is need for the constitution to make a categorical provision for informed consent in medical procedures, human subject research and even in clinical trials in Nigeria and provide enforcement modalities for a safer Nigeria.

II. The National Health Act, 2014.

The National Health Act 2014 (NHA) is a pivotal domestic statute that explicitly codifies informed consent in healthcare, establishing a national framework for health services regulation and patient rights. It mandates consent for treatments, research, and tissue removal, emphasizing user autonomy.

Section 23(1) of the National Health Act 2014 requires healthcare providers to give users relevant information on: (a) the user's health status except in circumstances where there is substantial evidence that the disclosure would be contrary to the best interests of the user; (b) the range of diagnostic procedures and treatment options generally available; (c) the benefits, risks, costs and consequences generally associated with each option; and (d) the user's right to refuse health services and explain the implications, risks or obligations of such refusal. This provision directly defines informed consent, requiring full disclosure to enable voluntary decisions. Implications include liability for providers who fail to inform, potentially leading to negligence claims.

Section 20(1) prohibits refusing emergency treatment, but Section 23(1)(d) affirms the right to refuse non-emergency services, balancing urgency with autonomy. While Section 32(1)(b) stipulates that Every research or experimentation on a living person shall only be conducted with the written consent of the person after he shall have been informed of the objects of the research or experimentation and any possible effect on his health. For minors, Section 32(2)(c) requires parental consent. This protects vulnerable groups, ensuring research consent is informed and written, with implications for ethical review boards. However, this section 32(2)(c) contradicts sections of the Child's Rights Act and the Supreme courts decision in Esabunor v Faweya (2019).

Part 1 of the Child's Rights Act on the best interest of the child principle provides as follows.

1. In every action concerning a child, whether undertaken by an individual, public or private body, institutions of service, court of law, or administrative or legislative authority, the best interest of the child shall be of paramount consideration.

2(1) A child shall be given such protection and care as is necessary for the well-being of the child, taking into account the rights and duties of the child's parents, legal guardians, or other individuals, institutions, services, agencies, organizations or bodies legally responsible for the child.

(2) Every person, institution, service, agency, organization and body responsible for the care or protection of children shall conform with the standards established by the appropriate authority particularly in the areas of safety, health, welfare, number and suitability of their staff and competent supervision.

By Section 13(1) of the Act, every child is entitled to enjoy the best attainable status of physical, mental and spiritual health. Every government, parent, guardian, institution, service, organization or body responsible for the care of a child shall endeavour to provide for the child the best attainable state of health(section13(2). The Act also in section 13(3)(a) enjoins government to endeavour to reduce infant and child mortality rate(section 13(3) a).

The Supreme Court of Nigeria in a kind of finality puts to rest this tension in *Esabunor & Anor. v Tunde Faweya & Ors(2019).* According to the facts of the case, the 2nd appellant was the mother of the 1st appellant, who was born on 19 April 1997 at the Chevron Clinic, Lekki Peninsula, Lagos. On 11 May 1997 the 1st appellant was sick and was taken to that Clinic which was owned by the 2nd respondent for treatment. The 1st respondent who was a medical doctor attached to the clinic examined the 1st appellant and found that the 1st appellant was suffering from severe infection which led to severe shortage of blood in his body. He therefore placed him on antibiotics and by the morning of 12 May, 1997, it was clear that the antibiotics were not working as the 1st appellant was convulsing and could not breathe properly and as such he was placed on oxygen therapy. It was at this stage that the medical personnel at the Chevron Clinic believed that without blood transfusion, the 1st appellant would die. The 1st respondent therefore informed the 2nd appellant that the life of the 1st appellant was in danger and only a blood transfusion could save his life. However, the 2nd appellant refused to consent to the transfusion of blood on the ground that she was a Jehovah 's Witness and blood transfusion was forbidden by her religion. The development was reported to the police by the management of the 2nd respondent. Thereafter, the 3rd respondent, on behalf of the 4th respondent, applied for and obtained an order from the Magistrate's Court presided over by the 5th respondent, authorizing the medical authorities of the 2nd respondent to do all that was necessary for the protection of the life and health of the 1st appellant. The order of the court was executed and the 1st appellant's condition improved so considerably that he was discharged a few days later. By an application dated the 15 May 1997, the 2nd appellant asked the 5th respondent to set aside the order of 12 May 1999 on the ground that it was fraudulently obtained. The application was dismissed as the order, having been complied with, could no longer be set aside.

The case went to the High Court, through the Court of Appeal and finally to the Supreme Court. Consistent with the reasoning of the Court of Appeal, the Supreme Court held:

> All adult persons have the inalienable right to make any choice they may decide to make and to assume the consequences. Accordingly, an adult person who is conscious and in full control of his mental capacity, and is of sound mind has the right to either accept or refuse medical treatment, including blood transfusion. In such case, the hospital has no choice but to respect the person's wishes. However, different considerations apply to a child because a child is incapable of making decisions for himself and law is duty bound to protect such a person from abuse of his rights even by the child's parents. So when a competent parent or a person *in loco parentis* refuses medical treatment or blood transfusion for a child on religious grounds, the court should step in. The court should take a decision after considering the child's welfare, i.e. saving the life of the child and the best interest of the child. These considerations outweigh whatever religious belief the parent of the child may have about any form of medical treatment because the child may grow up to reject his parent's religious beliefs. And the decision of the court should be to allow the administration of blood transfusion especially in life threatening situation. In this case, the 1st appellant was then only one month old, was incapable of deciding for himself. On the other hand, the 2nd appellant, his mother, acted on her religious belief. In the circumstance, the 5th respondent was right in granting the said 4th

respondent's application, which allowed the 1st respondent to save the life of the 1st appellant. (*Esabunor & Anor. v Tunde Faweya & Ors.*(2019).

Law exists primarily to protect life and preserve the fundamental right of citizens inclusive of infants. The Supreme Court anchored its decision on the provisions of the Child's Rights Act and noted that Section 13 of the Child's Right Act provides for the right to health and health service of the child. Going further with the National Health Act 2014 (NHA) Section 48(1)(a) which governs tissue removal states that A person shall not remove tissue, blood or blood product from the body of another living person for any purpose except: (a) with the informed consent of the person from whom the tissue, blood or blood product is removed granted in the prescribed manner. This extends to consent to organ donation and transfusions, with criminal penalties for violations. The extent to which this is enforced in Nigeria is simply a mirage. The National Health Act 2014 (NHA) by implication shifts from paternalistic medicine to patient-centered care, with enforcement through the Federal Ministry of Health and courts. However, challenges include low awareness and enforcement gaps in rural areas. There is need for health orientation especially in rural areas to reduce the high level of tissue or organ removal against consent in various parts of the country as business transaction.

III. Medical and Dental Practitioners Act/ Code of Ethics

The Medical and Dental Practitioners Act Cap M8 LFN 2004 regulates medical practice, establishing the Medical and Dental Council of Nigeria (MDCN) to enforce ethical standards, including informed consent via the Code of Medical Ethics (2008). Section 1 of the Act, establishes the MDCN to determine standards and investigate misconduct. The Code's Rule 19 mandates Practitioners involved in procedures requiring the consent of the patient to ensure that the appropriate consent is obtained before such procedures. Rule 28 deems failure to obtain consent of the patient (informed or otherwise) before proceeding on any surgical procedure or course of treatment, when such a consent was necessary as negligence. Rule 31 on research requires that Each subject must be informed of the aims, methods to be used and that he or she is at liberty to abstain. Rule 39 respects religious refusals. However, when a minor is involved, government comes in acording to the Childs Rights Act and the Supreme Court decision already canvassed in *Esabunor & Anor. v Tunde Faweya & Ors.* Thus, any violation or breach of the code leads to disciplinary actions, including license suspension.

IV. Patients' Rights Charter 2014

The Patients' Rights Charter 2014, is a policy under the Federal Ministry of Health which outlines 12 rights, including informed consent, to promote patient-centered care. Key rights in the Policy include the Right to information on health status and treatments; right to consent or refuse care; right to confidentiality; right to dignity and respect. It requires providers to obtain written consent for procedures, explaining risks and alternatives in understandable language. For emergencies, consent is waived but documented post-procedure.

5. Recommendations and Conclusion

Though there are parchments of provision in various statutes in Nigeria pointing to informed consent in medical procedures, human subject research, and clinical trials for drug research informed consent for capable adults should be primarily and categorically provided for and governed by the constitution of the Federal Republic of Nigeria as it is done in developed countries. All other laws draw their strength and validity from the constitutional provision but when the Constitution makes no categorical statement, it will be difficult to hold any defaulter criminally or tortuously responsible. The stakeholders will always interpret their policies according to their interest to protect their kind. Thereby, placing patients and victims at the mercy of reckless providers. It is common knowledge that the conduct of clinical trials for the development and licensing of drugs is a very important aspect of healthcare. Drug research, development and promotion like all areas of human endeavour involving control of huge financial resources, has become subject to deviant behaviour, sharp business practices and unethical conducts. Clinical trials should be adequately provided for in the constitution. With the increasing globalisation of research it is imperative that all players including consumers should be aware of the ethical challenges in clinical trials and the benchmarks for ethical conduct of clinical research in Nigeria.

References

- Bazzano L.A , Jaquail Durant, Paula Rhode Brantley (2025); A Modern History of Informed Consent and the Role of Key Information, OchsnerJournal ,https://pmc.ncbi.nlm.nih.gov/articles/PMC7993430/ accessed 26/2/26.
- Beauchamp T.L and Childress J.T, (2009) Principles of Biomedical Ethics, 6th edition, Oxford University Press,
- Canterbury v. Spence (1972) 464 F.2d 772 (D.C.Cir)
- Castell v. De Greef (1994) (4) SA 408 (C)
- Constitution of the Federal Republic of Nigeria (CFRN) 1999 (Fifth Alteration)
- Esabunor & Anor. v Tunde Faweya & Ors (2019)7 NWLR(Pt 1671) 316
- Loi Kouchner Law (2002)-303
- Medical and Dental Practitioners Act, Cap M8 Laws of the Federation of Nigeria 2004
- Medical and Dental Practitioners Disciplinary Tribunal v. Okonkwo, (2001) 7 NWLR (Pt 711) 206.
- Mohr v Williams (1905) 95 Minn 261, 104 NW 12 (1905). Accessed February 27, 2026. www.lexisnexis.com/community/casebrief/p/casebrief-mohr-v-williams
- Montgomery v. Lanarkshire Health Board (2015) UKSC 11.
- Natanson v. Kline (1960) 186 Kan 393
- National Health Act (2014)
- Nuremberg ,On August 20, 1947, See also: Permissible Medical Experiments. In: Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10. Vol 2. Washington, D.C.: US Government Printing Office; 1949:181-182
- Okpala P.(2019), 'Informed Consent and the Nigerian Patient: Ethical and Legal Perspectives' 5(1) Journal of Contemporary Law , 14.
- Onyegbule Kelechi Goodluck(2025); Informed Consent as a Fundamental Principle of Medical Ethics: An Examination of itsApplication in Nigerian Healthcare Settings, Nnamdi Azikiwe University Journal of Commercial and Property Law, Vol. 12 No. 1 , 160-171.

- Pratt v Davis (1905) 118 Ill App 161 (1905). Accessed 27/2/ 2026. www.ravellaw.com/opinions/967d63e3e4aceb0c7ccc62e78af2d543
- Reibl v. Hughes (1980) 2SCR 880.
- Rolater v Strain(1913) 39 Okla 572, 137 P 96 (1913). Accessed 27/2/2026. law.justia.com/cases/oklahoma/supreme-court/1913/14030.html.
- Salgo v Leland Stanford Jr University Board of Trustees(1957) 154 Cal App 2d 560, 317 P2d 170 (1957). Accessed February 28, 2026. caselaw.findlaw.com/ca-court-of-appeal/1759823.html
- Samira Kohli v. Dr. Manchanda Law No. 2002-303
- Schloendorff v. Society of New York Hospital 105vN.E 92, 93 (N.Y. 1914).
- Sidaway v. Bethlem Royal Hospital (1985) AC 87.
- The "Doctors Trial"(1947)-(USA v. Karl Brandt et al.). On August 19, 1947, the judges of the tribunal delivered their verdict. But before announcing the guilt or innocence of each defendant, they confronted the difficult question of medical experimentation on human beings.
- United States Holocaust Memorial Museum, Washington, DC;Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg, October 1946–APRIL 1949. Washington, D.C.: U.S. G.P.O, 1949–1953.
- World Health Organization (WHO 2016), Patient Safety: Making Health Care Safer (WHO 2016).