LEGAL BASIS FOR RESEARCH ETHICS GOVERNANCE IN NIGERIA

BY

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TITLE PAGE

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DEDICATION

TO

GOD ALMIGHTY
My Hiding Place

AND

To the memory of my late father

CHIEF EMMANUEL OYEDELE ASHAMU

ABSTRACT

Ethics can be described as moral philosophy. It seeks to address philosophical questions about morality. Ethics transcends various professions and with globalisation, ethics now cuts across all human endeavours. Law on its part is a system of rules which a society sets to maintain order and protect against harm to persons and property. The law establishes restrictions and requirements for behaviour and represents a general consensus of what is or is not ethical. Consequently, law acts as a guide for solving research ethics problems. Research can be defined as the search for knowledge, or as any systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

The ethical and legal framework for protecting human subjects in research rests on the principles of autonomy, beneficence and justice. Over the years, countries have developed and modified these guidelines and requirements to reinforce these theoretical principles. In Nigeria however, there is no singular law governing conduct of research. The laws governing research ethics in Nigeria are based on common law principles of equity, contract, tort and criminal law, and to a considerable extent on various legislations and the rules and regulations made pursuant to them.

This study seeks to examine the various laws regulating human subject research in Nigeria with a view to collating them into a document making them easily accessible to researcher.

Keywords: *ethics, law, research governance, human subjects.*

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CERTIFICATION PAGE

I certify that this work was carried out by Jadesola Oyetoro Lokulo-Sodipe in the Department of Surgery, University of Ibadan.

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LIST OF ABBREVIAITONS

1.	All ER	All England Report
2.	All NLR	All Nigerian Law Report
3.	AC	Appeal Cases
4.	CLR	Commercial Law Report
5.	GCP	Good Clinical Practice
6.	ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.
7.	ICH-GCP	International Conference on Harmonisation – Good Clinical Practice.
8.	LFN	Laws of the Federation
9.	NAFDAC	National Agency for Food and Drug Administration and Control
10.	NWLR	Nigerian Weekly Law Report
11.	SCM	Supreme Court Monthly
12.	SC	Supreme Court Report

GLOSSARY

Approval: the affirmative decision of the Research Ethics Committee (REC) that the clinical trial has been reviewed and may be conducted within the constraints set forth by the REC, the institution, Good Clinical Practice (GCP), and the applicable regulatory requirements.

Beneficence: the ethical obligation to maximize benefits and to minimize harm.

Benefit: the magnitude of a good outcome.

Clinical Trial/Study: an investigation in human subjects to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

Community: A community is a group of people understood as having a certain identity due to the sharing of common interests, values or to a shared proximity. It refers to a group of people living in the same village, town, or country and, sharing geographical proximity.

Confidentiality: this is principle according to which personal information can only be disclosed with informed consent of the person concerned and solely to authorised persons.

Conflict of interest: Conflict of interests is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity.

Good clinical practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

Data and Safety Monitoring Board: is an independent data-monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial.

Informed consent: Informed consent is a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation.

Investigator: A qualified scientist who undertakes scientific and ethical responsibility, either on his/her own behalf or on behalf of an organization/ firm, for the ethical and scientific integrity of a research project at a specific site or group of sites. In some instances a coordinating or principal investigator may be appointed as the responsible leader of a team of sub investigators.

Research Ethics Committee: An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility it is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and approving / providing favourable opinion on, the trial protocol, the suitability of the investigator(s), facilities, and the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

Research participant/subject: An individual who participates in a biomedical research project, either as the direct recipient of an intervention, as a control, or through observation.

Research: The term "research" refers to a class of activity designed to develop or contribute to generalizable knowledge. Generalizable knowledge consists of theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference. In the present context "research" includes both medical and behavioural studies pertaining to human health. Usually "research" is modified by the adjective "biomedical" to indicate its relation to health.

Vulnerability: Refers to a substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group.

INTRODUCTION

Ethics can be described as moral philosophy. It seeks to address philosophical questions about morality. Its history dates back to philosophy and religious writing[1]. Ethics is a theoretical framework for the analysis of human conduct (and there are philosophical, sociological and other theoretical frameworks). It is the general term covering several different ways of examining and understanding the moral life[2]. Ethics can be divided into two main types, namely, Normative Ethics and Non- normative ethics. Normative Ethics is a branch of ethics that investigates the set of questions that arise when we think about the question, 'how we ought to act morally?' It examines standards for the rightness and wrongness of actions. It is also known as prescriptive ethics[3]. Non-normative ethics, on its part has the objective of establishing what factually or conceptually the case is and what ethically *ought* to be the case or what is ethically valuable[4]. It is an analysis of the meaning of the terms used in moral discourse. Non – normative ethics can further be divided into Descriptive ethics, which is the factual investigation of moral belief, and conducts. It uses scientific techniques to study how people reason and act[5]; and Meta-ethics which involves analysis of the language, concepts and methods of reasoning in normative ethics[6].

[1] Karlberg, J P E., (2010)"Reviewing Clinical Trials: A guide for the Ethics Committee"., p.19. Retrieved from www.clinicaltrialmagnifier.com on 15th July, 2010.
[2]Beauchamp T L and Childress J F, (2009) Principles of Biomedical Ethics., New York., Oxford University Press., p.1.
[3] Ibid., pp. 1-2.
[4] Ibid., p.1.
[5] Ibid., p.2.
[6] Ibid., p.2.

Ethics transcends various professions such as law, priesthood, medicine, and the military. With globalisation however, ethics now cuts across all human endeavours. Ethics is now taken seriously in governance, business, academia, and other walks of life[7].

Law can be described as a system of rules a society sets to maintain order and protect against harm to persons and property. It is a set of rules established by a governing authority to institute and maintain orderly co-existence. The law establishes restrictions and requirements for behaviour and represents a general consensus of what is or is not ethical. Consequently, law acts as a guide for solving research ethics problems. Law however is more than corrective as it gives recognition to the social importance of research ethics.

The term "law" is used in many senses. We speak of the laws of science, football, mathematics, etc. However, when we speak of the law of a state we use the term "law" in a special and strict sense, and in that sense, law may be defined as a rule of conduct, imposed upon and enforced among, the members of a given state[8]. Law is a body of rules made for the guidance of human conduct. It may be classified in various ways, namely;

- Criminal Law and Civil Law
- Public Law and Private Law
- Substantive Law and Procedural Law
- Municipal Law and Public International Law.

For our purposes, we would classify law as criminal and civil.

[7] Erinosho O(ed), (2008)"Ethics for Public Health Research in Africa"., being Proceedings of an International Workshop in Collaboration with the Special Programme for Research and Training in Tropical Diseases (TDR) of the World Health Organisation, with the support of the Federal Ministry of Health, Abuja, Nigeria. April 21-23, 2008.
[8] Barker D and Padfield C., (1998)., Law., Read Educational and Professional Publishing Ltd, Oxford., p.1.

Criminal Law is that part of the law which characterises certain kinds of wrong doings as offences against the State. These wrongs, may not necessarily violence any private right, and are punishable by the State[9].

Civil law on its part is concerned with the rights and duties of individuals towards each other. It includes, Law of Contract, Law of Tort, Law of Property, Law of Succession and Family Law. The Laws of Contract and Tort have direct reflection on research ethics.

The Law of Contract is that branch of Law which determines whether a promise is legally enforceable and what are its legal consequences.

A tort is a civil wrong for which the remedy is a common law action for unliquidated, that is unspecified or unascertained damages and which is not exclusively the breach of a contract or breach of trust or other merely equitable obligation[10].

Laws are created through legislations called **statutory laws**, or by judges in court cases which are called **case laws.** Statutory laws comprise written laws enacted by either a state legislature or national assembly which are either civil or criminal. Case law comprises decisions of the various courts. These decisions determine the outcome of individual court cases by providing precedents to be followed in the interpretation of statutory laws and the Constitution[11].

Research can be defined as systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge[12].

[9] Ibid, p3.
[1010] Clerk and Lindsell on Torts (1982)., Sweet and Maxwell., London., p.1
[11] 1999 Constitution of the Federal Republic of Nigeria.
[12] National Code for Health Research Ethics, 2007.

The ethical and legal framework for protecting human subjects rests on the principles of autonomy, beneficence and justice. The first principle, autonomy, requires that subjects be treated with respects as autonomous agents. It also affirms that those persons with diminished autonomy are entitled to special protection. In practice, this principle is reflected in the process of informed consent, in which, prior to the commencement of the research, the risks and benefits of the research are disclosed to the subjects.

The second principle, beneficence, involves maximising possible benefits and good for the subjects, while minimising the amount of possible harm and risks resulting from the research. Benefits can be defined as gains to the society and contribution to the knowledge base for the individual through improved well being, or empowerment. Harm on the other hand, may include death and injury, psychological abuse, loss of privacy and public exposure. This could affect individuals, groups of people or even a large community.

Since the fruits of knowledge can come at a cost to those participating in research, the last principle, justice, seeks a fair distribution of the burdens and benefits associated with research. Thus certain individuals or groups would not bear disproportionate risks while others reap the benefits.

Over the years, guidelines and requirements such as informed consent and the protection of privacy and confidentiality, have been developed and modified to reinforce these universally accepted ethical principles highlighted above.

Statement of Problem

Research and Development (R&D) is on the increase all over the world. In Nigeria, increasingly, grants are being awarded for the R&D to various institutions. The laws governing research ethics in Nigeria are based on common law principles of equity, contract, tort and criminal law, and to a considerable extent on various legislations and the rules and regulations made pursuant to them.

There is no singular law governing conduct of research in Nigeria. The ethical and legal framework for protecting human subjects rests on the principles of autonomy, beneficence and justice. Consequently, students and researchers have to look into various aspects of the law to glean what is a relevant to given situation. Often times, they are not aware of the existence of a given regulation.

In view of the increase in R&D and the involvement of international groups, there is a need to compile these laws in a resource material for all stake holders.

Objective of the Study

The objective of this study is to examine the various laws regulating research in Nigeria with a view to compiling and codifying them. Secondly, the study is aimed at increasing knowledge in respect of the laws relating to management and conduct of ethics in research. . Lastly, it is hoped that it will strengthen research ethics evaluation capacities.

Methodology

Nigerian legal system comprises both case law and legislation. This work involves a research into the various laws applicable to research ethics. It is a literature research. This will involve an

examination of legal literature in Nigeria, legal and policy instruments that are relevant to research ethics. References will also be made to relevant case law.

In view of the fact that there are rules and regulations, draft bills and directives relating to research ethics which are only available at the agency concerned, visits will be made to such agencies to source for materials.

Expected Outcome

This research is expected to contribute to the area of the law relating to research ethics and compile a compendium of laws governing research ethics in Nigeria. The work will collate laws governing various aspects of research ethics such as ethics review criteria, oversight for ethics review, criteria for selecting research participants, issues relating to conflict of interest, privacy, risk-benefit ratio, compensation and informed consent process.

CHAPTER 1

NIGERIAN LAW AND RESEARCH ETHICS

1.1. The Nigerian Legal System

The Federal Republic of Nigeria (FRN) is a Constitutional Republic. At independence, Nigeria consisted of three regions, namely, the Northern Region, the Eastern Region and the Western Region. At present, Nigeria is made up of 36 states and a federal capital territory (FCT), located in Abuja. These states are, as a matter of convenience and political expediency grouped into 6 geopolitical zones of North East, North West, North Central, South East, South West, and South South[1]. This grouping has however not been accorded any constitutional recognition[2]. There are close to 400 linguistic groups in Nigeria, but the 3 major languages are Hausa, Igbo and Yoruba, while English is the official language.

The Nigerian Legal System (NLS) is based on the English Common Law and legal tradition by virtue of colonization and the attendant incidence of reception of English law through the process of legal transplant[3]. English law has a tremendous influence on the Nigerian legal system, and it forms a substantial part of Nigerian law. Section 32 (1) of the Interpretation Act[4] provides that, "*the common law of England and the doctrines of equity and the statutes of general application*

[1] Nigeria's Report on the Implementation of the Beijing Platform for Action and Commonwealth Plan of Action., Federal Ministry of Women Affairs (4/2004). Retrieved from www.thecommonwealth.org. on 24th February, 2010.
[2] Dina Y, Akintayo J, Ekundayo F., "Guide to Nigerian Legal Information"., Retrieved from www.nyulawglobal.org on 24th February, 2010.
[3] Obilade A O., (1979) The Nigerian Legal System., Ibadan., Sweet &Maxwell.
[4] Cap I23 Laws of the Federation(LFN), 2004.

which were in force in England on 1st January, 1900 are applicable in Nigeria, only in so far as local jurisdiction and circumstances shall permit"[5].

Consequently, legal issues evolving from common law in England and codes of conduct of the medical profession and professional ethics as a whole, such as confidentiality, consent, maleficence, beneficence, duty of care are applicable in Nigeria even though they have not been legislated upon[6].

1.1.1. Sources of Nigerian Law

The sources of Nigerian Law are as follows:

The Constitution- the Nigerian Constitution is a Federal one. A federal constitution is one which provides for division of powers between the constituents of the Federal Government[7].

The Nigerian Constitution is supreme[8]. Constitutional supremacy relates to the supremacy of authority of the constitution over other laws. Section 1(1) provides that, "*this Constitution and its provisions shall have binding force on all authorities and persons throughout the Federal Republic of Nigeria"*. In addition to this, Section 1(3) provides, "*if any other law is inconsistent with the provisions of this Constitution, this Constitution shall prevail and that other law shall to*

[5] See section 32 (1)&(2) Interpretation Act, Cap I 23,LFN, 2004.
[6] National Code of Health Research Ethics, 2007.
[7] Yakubu J A., (2003) Constitutional Law in Nigeria, Ibadan., Demyax Press Ltd., p. 10.
[8] See S.1 (1)&(3) 1999 Constitution of the FRN.

the extent of the inconsistency be void"[9]. The current Constitution is the 1999 Constitution which came into operation on 29th May, 1999.

By virtue of section 13(2)(b), the security and welfare of the people is the primary purpose of the government. Sections 15-21 set out the various ways in ensuring that this purpose is fulfilled without violating the fundamental rights of the citizens which are set out in Chapter 4 of the Constitution. These rights include, the right to life[10], right to dignity of persons[11], right to personal liberty[12], right to fair hearing[13], right to private and family life[14], right to freedom of thought, conscience and religion[15], right to freedom of expression and the press[16], right to peaceful assembly and association[17], right to freedom of movement[18], right to freedom from discrimination[19] and the right to acquire and own immovable property anywhere in Nigeria[20].

Legislation- The Constitution regulates the distribution of legislative business between the National Assembly which has power to make laws for the Federation and the House of Assembly of each state of the federation.

The current legislation in force at the Federal level is largely contained in the Laws of the Federation of Nigeria 2004 (LFN). Laws made subsequently are found in the annual volumes of

[9] See also *Abacha v Fawehinmi* (2005) 5 NWLR 29, where it was held *inter alia,* "it is necessary to get our bearing right. The Constitution is the supreme law of the land; it is the grundnorm. Its supremacy has never been called to question in ordinary circumstances".
[10] Section33 1999 Constitution
[11] Section 34 1999 Constitution.
[12] Section 35 1999 Constitution
[13] Section 36 1999 Constitution
[14] Section 37 1999 Constitution
[15] Section 38 1999 Constitution
[16] Section 39 1999 Constitution
[17] Section 40 1999 Constitution
[18] Section 41 1999 Constitution
[1919] Section 42 1999 Constitution
[20] Section 43 1999 Constitution

the laws of the FRN. Federal laws enacted under the military regime known as Decrees and state laws known as Edicts form the bulk of primary legislations.

English Law- this consists of:

a) The received English Law comprising of the following, the common law, the doctrine of equity, statutes of general application in force in England on January 1, 1900, Statutes and subsidiary legislation on specified matters, and
b) English law (statutes) made before 1st October, 1960 and extending to Nigeria which are not yet repealed. Laws made by the local colonial legislature are treated as part of the Nigerian legislation.

Despite the influence of English law, the Nigerian legal system is very complex because of legal pluralism. Legal pluralism is the existence of multiple legal systems within one geographic area. It occurs when different laws govern different groups within a country or where, to an extent, the legal systems of the indigenous population have been given some recognition. Legal pluralism is prevalent in former colonies, where the law of a former colonial authority may exist alongside traditional legal systems. This is evident in the Nigerian Legal system where the customary law exists side by side with the inherited English Legal System[21].

Customary Law: this emanated from the usage and practices of the people. The traditional classification of customary law is into the following categories:

- Ethnic/ Non – Muslim

[21] Dina F et al., ibid

- Muslim Law / Sharia

Muslim Law/ Sharia

In the southern part of the country, Muslim/ Islamic law, where it exists, is integrated into and has always been treated as an aspect of the customary law. Islamic law has however been in use in the Northern part of the country since 1959. Islamic/Sharia/Muslim Law is written with clearly defined and articulated principles. It is based on the Islamic religion and was introduced in Nigeria as a consequence of a successful process of Islamization. It is based on the Holy Koran and the teachings of the Prophet Mohammad.

Ethnic/Non-Muslim law is the indigenous law that applies to the members of the different ethnic groups. Nigeria is made up of several ethnic groups each with its own variety of customary law. Ethnic Customary law is unwritten, uncertain and difficult to ascertain. Ethnic Customary law is enforced in customary courts[22]. These courts are at the lowest rung of the hierarchy of courts and in most cases are presided over by non- legally trained personnel[23].

Judicial Precedent: This is an earlier happening, decision, etc, taken as an example or rule for what comes up later[24]. The doctrine of precedent is founded on the objective of law that ensures that like cases are decided alike. The operation of the doctrine is tied to the hierarchy of the courts. A court is bound by the decisions of any court above it in the hierarchy.. The

[22] These are known as area courts in the Northern part of Nigeria and Customary courts in the Southern part of the Country.
[23] These courts are included the class of inferior courts. Their establishment, jurisdiction and composition are generally at the discretion of the individual states. Each state has its own hierarchy of inferior courts made up of different grades as the appropriate state legislature may deem necessary to create.
[24] P U Umoh., (1984) Precedent in Nigerian Courts., Enugu, Fourth Dimension., p.5

Supreme Court is the highest court of the land[25]. The Court of Appeal[26] is the penultimate court to entertain appeals from the High Courts, which are the trial courts of general jurisdiction. The Court of Appeal and all lower courts are bound by the decision of the Supreme Court.

Judicial precedent does not apply to certain courts like the customary/area courts and the sharia courts.

Nigeria operates a dual court structure. The Federal and State courts are not in two parallel lines. It is only to a limited extent that it may be asserted that each state has its own legal system.

International Law

Nigeria is a member of the United Nations, the Commonwealth of Nations, African Union and many others. Although Nigeria is a signatory to various international conventions and covenants, these are not enforceable in Nigeria unless they are enacted into law by the National Assembly[27]. A list of such covenants, treaties and convention relating to research ethics will also be compiled in this study.

1.1.2. GOVERNMENT BODIES

The system of Government in the Republic of Nigeria is modelled after the American presidential system with three arms of government, namely, the legislature, the executive and the

[25] See Section 235 of the 1999 Constitution.
[26] See Section 237 (1) of the 1999 Constitution.
[27] See S.12 1999 Constitution.

judiciary[28]. This is known as 'Separation of powers'. Separation of powers is the division of government powers, namely, legislative, executive and judicial powers. The legislature[29] makes the law, the executive implements the law[30], while the judiciary interprets the law[31].

Legislature: Section 4 (1) of the Constitution provides that the legislative powers of the country shall be vested in the National Assembly. By virtue of Section 4 (2), the National Assembly has powers to make laws for the peace, order and good government of the federation, to the exclusion of the state House of Assembly. It follows law making procedures as specified in sections 58 and 59 of the 1999 Constitution. It is bicameral and is made up of the Senate and the House of Representatives. The powers of the National Assembly to legislate refer to:

i) Any matter included in the Exclusive Legislative list[32], to the exclusion of the State House of Assembly[33].
ii) Any matter in the concurrent legislature list set out in the first column of Part II of the Second Schedule of the Constitution to the extent prescribed in the second Column opposite[34]; and
iii) Any other matter with respect to which the National Assembly is empowered to make laws in accordance with the provisions of the Constitution.

Each state has its own law making organ known as the House of Assembly[35]. State Houses of Assembly have powers to legislate on any matter in the concurrent legislative list and any

[28] See Sections 4-6 1999 Constitution of the FRN
[29] See S.4 1999 Constitution.
[30] See S.5 1999 Constitution.
[31] See S.6 1999 Constitution.
[32] See Part 1 of the 2nd Schedule to the 1999 Constitution.
[33] See S.4(2) 1999 Constitution. See also *A.G Ondo State . v. A.G Federation* (2002) 9 NWLR (pt 772) 222.
[34] S. 4 (4) 1999 Constitution.

other matter with respect to which it is empowered to make laws in accordance with the provisions of the Constitution[36].

By virtue of S.4 (5), where there is inconsistency between a law made by the State House of Assembly and that of the National Assembly, the latter prevails and the former, to the extent of the inconsistency becomes void.

It is pertinent to note that scientific and technological research, including health research, falls within items on the concurrent list[37]. Consequently, both the National Assembly and a State House of Assembly may make laws governing research ethics in Nigeria.

Executive: the executive power of the Federation is vested in the President by virtue of section 5(1) of the 1999 Constitution. Such powers can be administered directly or through the Vice President or Ministers or officers of the government. In the states, the executive power of a state is vested in the Governor and may be exercised through the Deputy Governor or Commissioners or other public officers.

Judiciary: By virtue of section 6(1) of the 1999 Constitution, the following courts are established in the Federal Republic of Nigeria, Supreme Court, Court of Appeal, Federal High Court, High Court of the Federal Capital Territory (FCT), Abuja, High Court of a State, the Sharia Court of Appeal of the FCT, Abuja, a Sharia Court of Appeal of a state, the Customary Court of Appeal of the FCT, Abuja and the Customary Court of Appeal.

[35] S.4 (6) 1999 Constitution.
[36] See S. 7 1999 Constitution.
[37] Items 20-21, 2nd Schedule , Part II.

The courts established by the Constitution are the only superior courts of record in Nigeria[38]. The Constitution empowers the National Assembly and the House of Assembly to establish courts with subordinate jurisdiction to the High Court[39]. These courts are invariably inferior courts of record notwithstanding the status of the officer presiding in the courts.

1.1.3. STATUTORY INSTITUTIONS

Apart from the arms of government set up by the Constitution, there are institutions/ governmental bodies which are creation of statutes. These institutions such as the National Health Research Committee, and National Agency for Food and Drugs Administration and Control, are allowed to make rules, regulations, directives and bylaws pursuant to their enabling Acts and consequently are binding. These institutions are also empowered to institute various committees as necessary in carrying out their duties. Procedures devised for these committees have binding effects on all parties concerned.

1.2. Sources of Law Relating to Research Ethics in Nigeria

The legal basis for research ethics in Nigeria as with all other area of laws is created either through legislation which are called statutory laws or by opinions written by judges in court cases which is known as case law.

Statutory laws regulating research ethics in Nigeria can be found in the Constitution; legislations of the state and local government; federal enactments (regulations, codes, directives) and international treaties. Some of these regulations have their basis in customary law and practices. Also relevant are various sets of international research ethics guidelines, all of which are

[38] See Section 6(3) 1999 Constitution of the FRN
[39] See Section 6(4) 1999 Constitution of the FRN

statements of principles for investigators, but none of which have legal authority. The most widely consulted sets of guidelines include the Declaration of Helsinki, the Council for International Organizations of Medical Sciences Guidelines, and the Guidance on Good Clinical Practice. Existing guidelines also address specific research situations, such as epidemiological studies, biomedical studies, and pharmaceutical trials.

Case law comprises of decisions of the various courts on matters brought under different heads of the common law such as contract and torts. These decisions determine the outcome of individual cases thereby providing precedents to be followed in the interpretation of statutory laws and the Constitution.

1.2.1. Common Law and Research Ethics in Nigeria

As noted earlier, the common law influences research ethics in Nigeria. The two aspects of common law relevant are the laws of contract and tort. A duty arises from the agreement between the parties which in tort is independent of agreements and imposed upon the parties by the law. The duty in tort may also be covered by that in contract[40]. The relationship which exists between the researcher and study participants can be said to be contractual. This relationship differs from the one made in business world for its nature, existence and extent cannot be easily defined.

The law of tort arises from a wrong or a breach of a duty. This breach can be redressed by an action in court for damages. Relevant to research are trespass to person, which can take the form of assault or battery; and negligence.

[40] Olopade. O.,(2008) Law and Medical Practice., College Press and Publishers Ltd. Ibadan., p.107.

Trespass is the unauthorized intervention with a person[41]. Thus, touching a person without the person's consent, such as treatment without consent is an actionable wrong in battery[42]. What the law protects is the dignitary interest, which is the individual's bodily integrity. Consequently, injury need not result from the touching, nor does the individual need to be aware of the offensive interference when it occurred. An unwanted operation on a patient while he is unconscious would amount to battery.

Negligence is the failure to take due care; the law of unintended harmful action or omission. For there to be an action in negligence, there must be a legally established duty from the Defendant to the Plaintiff; a duty which the defendant must be in breach of, as a result of which the plaintiff has experienced an injury which entitles him to damages[43].

1.3. Criminal Liability in Research

By virtue of Sections 303-305 Criminal Code Act[44], every person who undertakes to administer surgical or medical treatment or do any other lawful act which is or may be dangerous to human life or health must have requisite skill and is expected to use reasonable care in doing such act.

Where an individual has the responsibility of doing an act, the omission of which is or may be dangerous to human life or health, he will be liable for any resulting consequence by reason of the omission to perform that duty. Where a violation of sections 303-305 of the Criminal Code Act results in the death, that individual will be liable under section 306 which provides that, "it

[41] *Dr R O M Okekerau . v. Danjuma Tanko* (2002) 9-10 SC 101.
[42] Supra.
[43] *International Messengers Nigeria Ltd. v . Engineer David Nwachukwu* (2004) 6-7 SC 88.
[44] Cap C38 LFN 2004.

will be unlawful to kill any person unless such killing is authorized or justified or excused by law".

These provisions not only impose a duty of care on researchers vis-à-vis research participants, but create criminal liability in respect of a breach of that duty.

Section 13 of the Corrupt Practices and Other Related Offences Act[45], makes it an offence for anyone, including sponsors of researchers to give or offer public officer gratification for their services.

1.4. Constitutional Provisions

As noted earlier the Nigerian Constitution is a Federal one. A federal constitution is one which provides for division of powers between the constituents of the Federal Government[46]. The Nigerian Constitution is supreme[47]. Constitutional supremacy relates to the supremacy of authority of the constitution over other laws.

Chapter 4 of the 1999 Constitution of the Federal Republic of Nigeria (CFRN) provides for the fundamental rights of citizens. The following touch on the rights of human subject research participants.

Section 17(1) of the 1999 CFRN, states that social order is founded on ideals of freedom, equality and justice. While **Section 17(2) (a)** provides that every citizen shall have equality of rights, obligations and opportunities before the law. By virtue of **Section 17(2)(b),** the sanctity of the human person shall be recognized and human dignity shall be maintained and enhanced.

[45] Cap C31 LFN
[46] Yakubu J A, (2003) Constitutional Law in Nigeria, Ibadan., Demyax Press Ltd., p. 10.
[47] See S.1 (1)&(3) 1999 Constitution of the FRN.

Section 17 (2)(d) prohibits exploitation of human or natural resources in any form whatsoever for reasons other than the good of the community.

The State, in **section 21** is obliged to protect, preserve and promote the Nigerian culture which enhances dignity and is consistent with the fundamental objectives as provided in the Constitution. This section relates to need to respect the cultural values of people vis-à-vis obtaining carrying out research in particular communities, especially in relation to obtaining consent.

Section 33 guarantees the right to life[48]. It provides that "every person has the right to life, and no one shall be deprived of his life, except in execution of the sentence of a court in respect of a criminal offence of which he has been found guilty in Nigeria".

Thus, a research participant must not be subjected to a study with the resultant effect of causing his or her death. It therefore pertinent, before a trial is initiated, foreseeable risks and inconveniences must be weighed against the anticipated benefit for the individual trial participant and community where appropriate[49].

By virtue of **Section 34** the right to human dignity is guaranteed. Section 34(1)(a) states that every individual is entitled to respect of the dignity of his person and accordingly no person shall be subjected to torture or to inhuman or degrading treatment". In line with the principle of autonomy, research must therefore respect and protect the rights and dignity of participants. The effect of this right is that a research participant has a right to be respected and treated in a dignify manner no matter the state of his health. He must not be treated in a brutal or dehumanizing way.

[48] See also Art.3 United Nations Declaration of Human Rights (UNDHR) 1948; Art. 6(1) International Covenant on Civil and Political Rights 1966; Art 4 African Charter on Human and Peoples' Rights 1981, which have all been ratified by Nigeria.
[49] Section 6(b) NAFDAC GCP Guidelines, 2009; Section F(d)(3) NCHRE, 2007.

The right to personal liberty is guaranteed by **section 35 of the 1999 CFRN**. It provides *inter alia* that, every person shall be entitled to his personal liberty and no one shall be deprived of such liberty except in some cases and in accordance with a procedure permitted by law. The Constitution by the above provision vests in an individual, the right to his personal liberty, and he must not be deprived of this right whether within or outside of the confine of a hospital except where the deprivation of liberty is justified.

By way of exception, a person may be deprived of his liberty in the case of persons suffering from infectious or contagious disease, person of unsound mind, person addicted to drugs or alcohol or vagrants, for the purpose of their care and treatment or protection of the community.[50]

Also entrenched in the 1999 Constitution are the rights to privacy and family life; and freedom of thought, conscience and religious. All these are preserved in section 37 and 38 of the 1999 Constitution respectively.

The right to privacy implies a right to protect one's thought, conscience or religious belief and practice from coercive and unjustified intrusion; and, one's body from unauthorized invasion.

The right to freedom of thought, conscience and religion implies a right not to be prevented, without lawful justification, from choosing the course of one's life, fashioned on what one believes in, and a right not to be coerced into acting contrary to one's life, religious belief. The limits of these freedoms, as in all cases, are where they impinge on the rights of others or where they put the welfare of the society or public health in jeopardy. The sum total of the rights of privacy and of freedom of thought, conscience or

[50] See section 35(1)(e) of the Constitution.

religion which an individual has, put in a nutshell, is that an individual should be left alone to choose a course for his life, unless a clear and compelling overriding state interest justifies the contrary[51].

The right to privacy is also concerned with access to personal records. Participants' right to privacy must be protected. The researcher must therefore ensure that, where personal information about research participants or a community are collected, stored, used or destroyed, it should be done in ways that respect the privacy or confidentiality of those concerned.

Informed consent must be obtained without duress or coercion and the researcher must not take advantage of the vulnerability of the research subjects.

Section 42 makes provision for the right to freedom from discrimination. It provides thus:

"(1) A citizen of Nigeria of a particular community, ethnic group, place of origin, sex, religion or political opinion shall not, by reason only that he is such a person-

(a) be subjected either expressly by, or in the practical application of, any law in force in Nigeria or any executive or administrative action of the Government, to disabilities or restrictions to which citizens of Nigeria of other communities, ethnic groups, places of origin, sex, religious or political opinions are not made subject; or

[51] Per Ayoola, JSC in *Medical and Dental Practitioners Disciplinary Tribunal v Dr John E.N. Okonkwo* (2001) SCM 78 (SC).

(b) be accorded either expressly by, or in the practical application of, any law in force in Nigeria or any such executive or administrative action, any privilege or advantage that is not accorded to citizens of Nigeria of other communities, ethnic groups, places of origin, sex, religious or political opinions.

(2) No citizen of Nigeria shall be subjected to any disability or deprivation merely by reason of the circumstances of his birth."

This provision relates to selection criteria to be used in research. The selection, recruitment, exclusion and inclusion of research participants in a research project must be just and fair, based on sound scientific and ethical principles. No person should be excluded inappropriately or unjustly on the foundation of race, age, sexual orientation, disability, education, religious beliefs, pregnancy, marital status, ethnic or social origin, conscience, belief and language[52].

1.5. Informed Consent[53]

Informed Consent is a process of reaching a decision after receiving adequate information sufficient for a reasonable person to take an informed decision. Issues involved in informed consent are, disclosure, substantial understanding (i.e recognition that consent is an act of authorization), voluntariness (free from other's influence, coercion, fear, use of force), competence (ability to perform a task), and consent. Informed consent must be obtained only for

[52] See also Section F (c) NCHRE, 2007; Art 6.5 ICH Guidelines for GCP [E6(R1)], 1996; Arts. 7(1) & 10 UN Declaration on the Rights of Disabled Persons (UNDRDP),1975

[53] See sections 17(2), 34,38 1999 CFRN; Section 7(1) Child's Right Act, Cap C50 LFN; Sections E (s)(1)(i), F(f)(1-13) NCHRE, 2007; Sections 4,6(i) NAFDAC GCP Guidelines, 2009.

the purpose and nature of the study. Informed Consent is an integral aspect of research involving humans. It raises issues of right to self-determination and bothers on rights of the individual as a person with rights to dignity and privacy amongst other rights. It safeguards the interests of both the researcher and the study participants. It raises the issue of disclosure, competence and authority. The Informed Consent process is inherently legal on the part of the participants, researchers and institutions concerned.

Informed Consent is therefore, an agreement obtained after a procedure in a study has been sufficiently explained to a prospective participant to the level of him making quality judgment on whether to participate in the study or not.

As noted earlier, the legal justification of informed consent in Nigeria is founded three areas of the law – contracts, tort and constitutional[54].

1.6. RESEARCH ETHICS GOVERNANCE PRE-2006

The pre-2006 era of research oversight in Nigeria was characterised by formal and informal mechanisms which included regulations by the federal government through agencies created for that purpose, review by ethics review bodies in research institutions, self-regulatory bodies in research institutions, and regulations by medical practitioners[55]. There were no general guidelines dealing specifically with the major ethical concerns which arise in relation to research in developing countries. Similarly, there were no laws or general guidelines requiring that

[54] See sections 17(2), 34, 35, 37, 38 1999 CFRN.
[55] C Onyemelukwe, (2008) "Regulating Research Involving Humans in Nigeria: Some Recent Improvements"., Health Law Review – 16:4. Retrieved from www.law.ulalberta.ca, on 24th Feb, 2010.

structure or composition and functions. Be that as it may, there existed ethics review committees which conducted reviews of research involving humans amongst others[56].

At this time, clinical research involving drug trials was regulated by the National Agency for Food and Drug Administration and Control (NAFDAC)[57]. NAFDAC is saddled with the responsibility of ensuring drug safety and compliance with approved specifications and quality and regulating the importation, exportation, and manufacture of drugs. In carrying out these functions it has powers to compile standard specifications, guidelines and regulations for the production of drugs, establishing and maintaining laboratories[58].

In exercising these powers, NAFDAC issued a set of guidelines for regulating clinical drug trials in Nigeria[59].

1.7. RESEARCH ETHICS GOVERNANCE POST-2006

The major development in research ethics in Nigeria post – 2006 is the inauguration of the National Health Research Ethics Committee (NHREC)[60]. In order to enhance its functions, the committee, drew up the National Code for Health Research Ethics, which applies to all health research involving human participants, conducted, supported or otherwise subject to regulation

[56] An example is the Nigerian Institute for Medical Research which was established by the Research Institute (Establishment Act) Order of 29th Sept, 1977.
[57] S.1 NAFDAC Act , No. 15 of 1993 (now Cap N1 LFN 2004).
[58] SS.5 and 29 NAFDAC Act.
[59] See the Introduction section of the NAFDAC Clinical Trials of Drugs in Nigeria: Guidelines, Procedures and Protocols.
[60] S.31 National Health Bill, 2008.

by any institution in Nigeria[61]. The effect of this development is that the NHREC operates at the national level, while the Health Research Ethics Committees (HRECs) operate at the institutional levels, reporting to the NHREC[62].

1.8. NATIONAL HEALTH BILL

The National Health Bill (the Bill) is a bill for an Act to provide a framework for the regulation, development and management of a national health system and set standards for rendering health services and other matters in the Federation. The Bill, amongst others establishes a National Health System[63], and makes provisions for the functions of the Federal Ministry of Health[64]. With regards biomedical research, the Bill makes provisions for the establishment of the National Health Research Ethics Committee[65]. Section 32 of the Bill regulates the conduct of research or experimentation with human subjects. Section 34 makes provision for the establishment of Institutional Health Research Committees. The Bill also makes provisions relating to uses of blood, blood products, tissue and gametes.

The Bill is a welcome improvement on the existing law. It however needs Presidential Assent for it to become law.

[61] Section B National Code for Health Research Ethics.
[62] www.nhrec.net.
[63] S.1 National Health Bill
[64] S.2 National Health Bill.
[65] S.31 National Health Bill

CHAPTER 2

TYPES OF RESEARCH: AN IN-DEPTH ANALYSIS

Research can be classified as applied, basic, directed and biomedical. The different types of research are being conducted in Nigeria. Researchers must however comply with laid down laws, principles, and guidelines [1]to ensure that research is scientifically sound. The Federal Ministry of Science and Technology was saddled with the responsibility of monitoring and co-ordinating research and development issues in Nigeria[2]. However, 1988 witnessed a reorganisation of the civil service by the Federal Government for effective, efficient and productive service. This resulted in the creation of the Department of Planning, Research and Development (DPRS) in all ministries[3]. With regards to research involving children, the Technical Advisory Committee has the function of advising the Federal Ministry of Health on policy formulation, promotion, co-ordination, and monitoring of research programmes[4]. The Federal Ministry of Health may initiate and support research activities relevant to the development of the child together with institutions, Non-governmental organisations and private sector[5].

2.1. Biomedical Research

Biomedical Research can be divided into two general categories, namely:

[1] These include the NCHREC, 2007; NAFDAC GCP Guidelines, 2009.
[2] Science and Technology Act, 1980.
[3] The National Strategic Health Development Plan Framework (2nd Draft). Obtained from the Ministry of Health, Oyo State, Nigeria.
[4] Para 3.4 of the Draft National Child Health Policy, 2006. Retrieved from www.fmh.gov.ng on 23rd Feb, 2010.
[5] Para. 4.1.6 of the Draft National Child Health Policy, 2006

a) Therapeutic Procedures which are intervention administered with the intent of providing direct benefits to the research participants.
b) Non-Therapeutic Procedures which are interventions that are not administered with therapeutic intent and are only intended to answer the scientific questions of the study.[6]

Health research must be scientifically sound to be ethical. Before clinical research can be conducted on humans in Nigeria, it must be both scientifically sound and ethical.[7]

The Research Unit within the Department of Health Planning, Research and Statistics of the Federal Ministry of Health, co-ordinates issues concerning health research in Nigeria[8]. Be that as it may, various Institutes co-ordinate different aspects of research[9].

2.1.1 Clinical Trials

A clinical trial may be defined as any investigation on participants intended to discover or verify the clinical, pharmacological and /or other pharmacodynamic effects of one or more investigational medicinal products, and /or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy[10].

[6] Section A, NHREC Code.
[7] Section A, NHREC Code; S.5 Food, Drugs and Related Products (Registration, etc) Act, Cap. 33, LFN; S.2(2) Child's Right Act. Cap.C50 Laws of Federation; S. 6(1) (e), S. 6(2)(a) National Agency for the Control of HIV/AIDS Act, 2008; NIMR IRB Guidelines for Applicants.
[8] Federal Ministry of Health, Nigeria Online Health Research Database; www.nhrd.gov.ng.
[9] SS.1.(1), 3(a)-(e) National Institute for Pharmaceutical Research and Development Act; SS.1 and 4 Research Institutes (Establishment etc) Order of 29th Sept, 1977; S3(1) Scientific and Industrial Research Act, Cap 53 LFN 2004; National Primary Health Care Development Agency Act, Cap N69 LFN 2004; National Eye Centre Act, Cap N38, LFN 2004.
[10] S.36 NAFDAC Good Clinical Practice Regulations 2009.

Clinical trials would be illegal unless the investigators ensure the benefits and safety of participants prior to the commencement of the trial. The investigators must weigh the foreseeable risks and inconveniences against the anticipated benefit for the individual trial participant and other present or future patients[11]. Anticipated benefits must justify the risks.

Other ethical requirements are:

- Rights, safety, and well-being of the trial participants are the most important considerations and shall prevail over interests of science and society.
- The available non-clinical and clinical information on an investigational medicinal product must be adequate to support the clinical trial.
- Clinical trials must be scientifically sound, and described in a clear, detailed protocol.
- Trials to be conducted in compliance with the approved protocol.
- Medical care given to, and medical decisions made on behalf of participants must be the responsibility of a qualified doctor or, when appropriate a qualified dentist.
- Freely given informed consent must be obtained from every participant prior to clinical trial.
- All clinical trial information must be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
- Privacy and confidentiality of records that could identify participants must be maintained.

[11] S.6 NAFDAC GCP Regulations 2009.

The investigators are expected to seek participants' views and consent before commencing the research. This is hinged on the right to freedom of opinion, expression and the right to personal liberty.[12] Failure to obtain consent may also constitute an actionable wrong of battery in the law of torts. 'Battery' is the intentional application of force to another person[13].

Where death and injury is occasioned as a result of failure to comply with ethical guidelines, it is a ground for civil and /or criminal liability which can be founded on the breach of duty of care[14], professional misconduct[15] or assault.

2.1.1.1 Clinical Drug Trials

Section 5 of the Food, Drugs and Related Products (Registration, etc) Act[16], empowers NAFDAC to regulate and control clinical trials in Nigeria. S.5 (1) provides that, no person shall in the course of his business:

a) Import or supply a drug, drug product, cosmetic or medical device.
b) Procure the manufacture or assembly of a drug, drug product, cosmetic or medical doctor.
c) Procure the importation or supply of a drug, drug product, cosmetic or medical device for the purpose of a clinical test unless he is a holder of a valid clinical trial certificate and the trial is to be carried out in accordance with the terms of the certificate and the provisions of any regulation in force.

Application for clinical trial certificates is to be made to NAFDAC in the prescribed manner[17].

[12] SS. 34, 37,39 1999 Constitution; Art 4, 5, 9 African Charter on Human and Peoples' Right (Ratification and Enforcement) Act, Cap A9; S.4 NAFDAC GCP Guidelines 2009; S.11 Child's Rights Act, Cap C50 LFN 2004.
[13] *Dr R O M . Okekearu v Danjuma Tanko* (2002) 9-10 SC 101.
[14] *International Messengers Nigeria Ltd v Engineer David Nwachukwu* (2004) 6-7 SC 88.
[15] *Medical & Dental Practitioners Disciplinary Tribunal .v. Okonkwo* (2001) SCM 78 (SC) .
[16] Cap F33 LFN 2004.

Where there is a contractual agreement between a sponsor and a Principal investigator conducting a clinical trial, such contractual agreement must be approved by the Head of the Institution in which the trial is being conducted or designee appointed for that purpose[18].

Clinical trials in Nigeria must comply with Good Clinical Practice (GCP), and the international standards laid down by Belmont Report, CIOMS, Declaration of Helsinki, UNESCO and other international guidelines[19]. There are also various local Acts and guidelines that govern the conduct of clinical trials in Nigeria[20].

2.1.1.2. Other Clinical Trials

These are regulated by provisions of various laws. These include:

a). Radioprotection

With regards to Radioprotection, the Radiographers (Registration, etc) Act[21], the Nuclear Safety and Radiation Protection Act[22] and the Regulations[23] made pursuant to the latter Act, set out standards of conduct governing exposure to radiation, imaging, professional qualification and level of protection to be given to human subjects against injurious radiation.

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[17] S.5(2) Food, Drugs and Related Products (Registration, etc) Act, CapF33 LFN 2004 .
[18] S,E (o) National Code of Health Research Ethics.
[19] NAFDAC GCP Guidelines, 2009; NIMR Guidelines.
[20] NAFDAC Guidelines on Good Clinical Practice (GCP) 2009 made pursuant to SS.5 & 29 NAFDAC Act Cap N1 LFN 2004; S.5 Food Drugs and Related Products (Registration, etc) Act Cap F33 LFN 2004; The Nigerian Institute for Medical Research (NIMR) Guidelines for Submission of Protocols; S2(2) Child's Right Act Cap C50 LFN 2004; Paragraph 12, Appendix 8 "General Principles of the Ethics of the Medical and Dental Practice in Nigeria" Medical and Dental Practitioners Act, Cap M8 LFN 2004; The Constitution of the Federal Republic of Nigeria 1999; S.32 National Health Bill 2008; S.31 Code of Medical Ethics in Nigeria – Rules of Professional Conduct for Medical and Dental Practitioners made pursuant to S.2(c) Medical and Dental Practitioners Act, Cap M8 LFN 2004;
[21] SS. 10, 18-21 Cap R1 LFN 2004.
[22] S.4(1) (b-d); S.S.18,21,25 Cap. N142 LFN 2004.
[23] SS. 4(1) &(2), 6(1), 9 Nigerian Safety and Security of Radioactive Sources Regulations, 2006; SS.4,9,10,28,35(1)(a) Nigerian Radiation Safety in Nuclear Medicine Regulation, 2006; SS. 4-69 Nigerian Radiation Safety in Radiotherapy Regulations, 2006.

The Criminal Code Act[24]requires every person who, except in the case of necessity, undertakes to administer surgical or medical treatment or to do any other lawful act which is or may be dangerous to human life or health, to have reasonable skill and to use reasonable care in doing such act[25]. S. 305 provides that when a person, whose duty it is to do an act, undertakes to do any act the omission to do which is or may be dangerous to human life or health, he will be liable for any resulting consequence by reason of the omission to perform the duty[26].

b). Transplantation

The National Health Bill 2008[27] makes provision for laws governing blood, tissue or blood product transplant. This must be done with the informed and written consent of the donor and in accordance with the conditions prescribed by the appropriate authority[28]. Transplantation must be done in a hospital authorised for that purpose and by a medical practitioner[29]. The tissue, blood or blood product removed may be used only for medical or dental purposes[30]. Where a donor has not given consent or where the tissue is one that cannot be replaced by natural process for a person under the age of 18, the tissue may not be removed[31]. A donor may however revoke his consent at any time prior to the removal of the relevant organ[32]. In addition, other ethical guidelines would also apply. It is expected that the risks involved would have been explained to the parties concerned and they are then given the opportunity to voluntarily consent to the procedure. The medical practitioners involved owe a duty of care to the patients in carrying out

[24] Cap C38 LFN 2004.
[25] S. 303 Criminal Code Act, Cap C38 LFN 2004.
[26] See also S.304 Criminal Code Act Cap C38 LFN 2004.
[27] The National Health Bill 2008 is awaiting Presidential Assent. It is therefore not yet binding on all concerned.
[28] S.49 National Health Bill 2008. Retrieved from www.nassnig.ng on 13th March, 2010.
[29] SS.52and 53 National Health Bill 2008.
[30] S.50(1) National Health Bill, 2008.
[31] S. 50(2) National Health Bill, 2008.
[32] S.58 National Health Bill 2008.

the transplant. The best interest of the patient given the prevailing circumstances must be considered before the transplant is done[33].

2.1.2. Research with human biological material

Transfer of samples and biological materials such as animals, herbs, and plants out of Nigeria requires a Material Transfer Agreement (MTA) detailing the type of materials, anticipated use, location of storage outside Nigeria, duration of such storage, limitations of use, transfer and termination of use of such materials subject to any law, and enactment in Nigeria[34]. The HREC concerned is expected to review the MTA to ensure consistency with the stated objectives of the research, the contents of the informed consent documents and other principles. The HREC grants provisional approval pending receipt of acknowledgement from the NHREC. Final approval is granted by the HREC following receipt of the acknowledgement and compliance with all other criteria[35].

The National Health Bill, 2008 and the Federal Ministry of Health's Nigerian Blood Policy 2005[36] make provision for transporting, storing and scientific disposition of human biological materials such as blood, gamete, etc. Section 51(a) and (b) of the 2008 Bill prohibits reproductive or therapeutic cloning without the approval of the Minister. Importation and exportation of human zygotes or embryos must be done only with the prior written approval of the Minister and on the recommendation of the National Ethics Research Committee[37].

[33] SS. 33 & 34 1999 Constitution; SS. 11&13 Child's Right Act, Cap C50 LFN 2004; SS. 6(1), 10 Rules of Professional Conduct for Medical and Dental Practitioners in Nigeria; SS. 303-305 Criminal Code Act, C38 LFN 2004.
[34] S.E(n) National Code of Health Research Ethics.
[35] S.E(n)(2),(4),(5) National Code of Health Research Ethics.
[36] Retrieved from www.fmh.gov.ng on 15th March, 2010.
[37] S.51(2) National Health Research Bill.

The Nigerian National Blood Policy standardizes the methods of collection, transportation, processing, testing, storage, distribution of blood and blood components and derivatives which are safe for transfusion and other medical therapy[38]. National cross-border exchange of blood and blood products may be done under the authority of a registered medical practitioner[39]. All health personnel handling and/or administering blood and blood products are expected to observe the National Blood Service Technical Guidelines for appropriate record keeping and haemovigilance.

2.1.3. Epidemiological studies

Research protocols for epidemiological studies must protect the welfare and rights of research participants and reflect the basic ethical principles of respect for persons, beneficence and justice. It must be detailed enough for a proposed participant to make a decision as to whether or not he/she would participate in the study[40].

[38] Para 9 Nigerian National Blood Policy, 2005.
[39] Para 55 Nigerian National Blood Policy, 2005.
[40] Belmont Report ; NAFDAC Good Clinical Practice Regulations 2009; S.32 National Health Bill 2008; SS. 33&34 1999 Constitution.

2.2. Research involving humans other than health research

Other human subject researches include those related to the environment, wildlife, agriculture education and animals. Same ethical principles that apply to biomedical research would also apply to this species of research[41].

[41] SS.1,2&4 Environmental Impact Assessment Act Cap E12 LFN 2004; Animal Disease (Control) Act Cap A17 LFN 2004; S.5(h) Directorate of Food, Roads and Rural Infrastructure Act Cap D10 LFN 2004; S.7(a)-(m) National Environmental Standards and Regulations Enforcement Agency (Establishment) Act, Cap N164 LFN 2004; Public Health Laws of the various states. NAFDAC Good Laboratory Practice Regulations, 2008.

CHAPTER 3

ETHICS REVIEW: DESCRIPTION, ROLE AND IMPORTANCE

For research to generate intended knowledge, produce benefit and justify the exposure of research subjects to burdens or risks, it must be valid. It is therefore essential and indeed a requirement of the law that the ethical and scientific rigour of all research projects conducted in Nigeria must be reviewed by a Nigerian based ethical review committee[1]. All research involving human participants conducted in Nigeria must be revised by an ethics committee, and where appropriate by the National Agency for Food, Drug Administration and Control (NAFDAC)[2]. The Research Unit within the Department of Health Planning, Research and Statistics, Federal Ministry of Health, co-ordinates issues concerning health research in Nigeria[3]. Be that as it may, various Institutes co-ordinates different aspects of research[4].

3.1. RESEARCH ETHICS COMMITTEE

An Ethics Committee reviews and subsequently approves or rejects research protocols submitted by investigators/researchers (investigators). There are different kinds of Ethics Committees. Some review protocols for animal studies, some for human studies in social sciences such as psychology and education, and others for clinical trials in patients or healthy volunteers.

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[1] SS. A, E (d) (i) NHREC; S.3(c) NAFDAC GCP Regulations; S.34 (2) National Health Bill, 2008.
[2] S. 5. NAFDAC Act. NAFDAC regulates and controls quality for standards for foods, drugs, cosmetics, medical devices, chemicals, detergents, and packaged water and chemicals advertised, exported, imported, manufactured locally and distributed in Nigeria.
[3] Federal Ministry of Health, Nigeria Online Health Research Database; www.nhrd.gov.ng.
[4] SS.1.(1), 3(a)-(e) National Institute for Pharmaceutical Research and Development Act, ; SS.1 and 4 Research Institutes (Establishment etc) Order of 29th Sept, 1977; S3(1) Scientific and Industrial Research Act, Cap 53 LFN 2004; National Primary Health Care Development Agency Act, Cap N69 LFN 2004; National Eye Centre Act, Cap N38, LFN 2004

In Nigeria, the various institutions have their research ethics committees which are known as institutional **review boards** (IRBs) or ethical **review committees (**ERCs). The National Health Research Ethics Committee (NHREC) is however the apex body responsible for the provision of and adherence to guidelines that govern ethical research practice in order to ensure the protection of human research participants.

3.1.1 NATIONAL RESEARCH ETHICS COMMITTEE

Since ethical guidelines are not administrative or legal documents, the conscience of researchers must be the best guide for ensuring that ethics are followed in research and clinical practice and for resolving ethical dilemma. However, there are appropriately constituted bodies at the institutional, local, regional and national levels to ensure that ethical guidelines are closely followed in the conduct of research and clinical practice.

S. 31 of the National Health Bill establishes the National Health Research Committee (NHREC) to amongst others, determine the extent of health research to be carried out by public and private health authorities in Nigeria[5]. In carrying out its role, the NHREC issued the National Code of Health Research Ethics. Health research conducted anywhere in Nigeria must comply with the provisions of the code[6]. All Health Research Ethics Committee in Nigeria must register with the NHREC[7] and are subject to accreditation process and criteria as may be determined by the NHREC. The NHREC is to advise the Minister for Health on the management of research ethics in Nigeria[8]

[5] S31 (5)(a).
[6] S. A. National Code of Health Research Ethics
[7] S. C. National Code of Health Research Ethics.
[8] S.31(5)(c) National Health Bill, 2008.

Primarily, the role of the NHREC is to promote good ethical practice in Nigerian scientific research, safeguard the dignity, right, safety and well-being of all actual or potential research participants through the auditing and accreditation of HRECs. In addition, it would provide guidance, training, and support to HRECs. The purpose of auditing and accrediting of the HRECs ethical review practices is to assist them in reviewing their practices and appraising performance while also providing a means to assure the public that the ethical review of research proposals is carried out according to established standards.

The Minister may however prescribe the manner in which the NHREC conducts its affairs and the procedure to be followed at its meeting, including the manner in which decisions are to be made and implemented[9].

3.1.1.1 JURISDICTION OF THE NHREC

The National Health Research Ethics Committee is the apex body responsible for the provision of and ensuring adherence to guidelines that govern ethical research practice in order to ensure the protection of human research participants in Nigeria[10].

3.1.1.2. COMPOSITION OF NHREC[11]

The NHREC consists of not more than 15 persons, namely –

a) A chairman
b) A medical doctor
c) A legal practitioner

[9] S.31(6) National Health Bill, 2008.
[10] www.nhrec.net.
[11] S.33(2) National Health Bill, 2008.

d) A pharmacist

e) A nurse

f) Not less than 2 religious leaders representing the Christian and Muslim religions

g) A community health worker

h) One researcher in the medical field

i) One researcher in the pharmaceutical field; and

j) Three other persons, one of who shall be a woman who in the opinion of the Minister are of unquestionable integrity.

A member of the NHREC may serve for a term of 3 years in the first instance and may be reappointed for another term of 3 years and no more under such terms and conditions as may be specified in his letter of appointment[12].

A member may vacate his office if he resigns or is requested in the interest of the public by the Minister to do so[13].

3.1.1.3. FUNCTIONS OF THE NHREC

The functions of the NHREC, enumerated in the National Health Bill and NHREC are as follows:

1). Determine the guidelines to be followed for the functioning of Institutional health research ethics committees;

2). Set norms and standards for conducting research on humans and animals, including clinical trials;

[12] S.33(3) National Health Bill.
[13] S.33(6) National Health Bill, 2008.

3). Adjudicate in complaints about the functioning of health research ethics committees and hear any complaint by a researcher who believes that he has been discriminated against by any of the health research ethics committees;

4). Register and audits the activities of health research committees;

5). Refer to the relevant statutory health professional council, matters involving the violation or potential violation of an ethical or professional rule by a health care provider;

6). Recommend to the appropriate regulatory body such disciplinary action as may be prescribed or permissible by law against any person found to be in violation of any norms and standards, or guidelines, set for the conduct of research under this Act; and,

7). Advise the Federal Ministry of Health and State Ministries of Health on any ethical issues concerning research on health[14].

3.1.1.4. NHREC OVERSIGHT OF HREC FUNCTIONS[15]

As part of the duties of the NHREC, it exercises oversight of the functions of HREC functions. This is to promote the health and well being of research participants. In carrying out this function, the NHREC;

a) Has powers to review annual reports of HREC functions and in addition may:

(1) Record attendance at HREC meetings to ensure that forums are formed, membership is diverse and outsiders are co-opted as indicated etc;

(2) Record all materials pertinent to approval of research and their determinations.

[14] S.33(6) National Health Bill, 2008.

[15] Section L National Code of Health Research Ethics, 2007.

(b) Reviews materials from HREC to ensure that registration status is maintained.

(c) Reviews the commitment of institution(s) to provide resources for proper functioning of HREC.

(d) At its own discretion, may conduct oversight visits to HRECs.

(e) May institute disciplinary action including suspension of registration, debarment from review of all or certain categories of research or any such action as it may deem fit against HREC that is found to be in violation of this code.

(f) Any dispute arising from any quarters, including research participants, researchers, sponsors, institutional officials or any other source, about the appropriate interpretations or intentions of any section of this code, other than matters of legality, shall be referred to NHREC for clarification and elaboration.

(g) Conducts any other activities in the exercise of its functions as enumerated in the relevant laws and guidelines.

3.1.1.5 PROCESS OF NHREC REVIEW OF RESEARCH[16]

The NHREC may decide to review a research where:

(a) The research is nation-wide in coverage or

[16] Section E (q) National Code of Health Research Ethics, 2007

(b) The research involves more than 3 sites in Nigeria or

(c) The research was referred to NHREC by HREC(s) or

(d) There is no HREC in an institution and the institution does not have a HREC cooperative agreement or

(e) The researcher considers the researcher of such complexity that there may be inadequate expertise in any one local institution or

At its discretion, the NHREC may review research by:

(a) Mandating review by any HREC in the country to act as a "HREC of record" and review the research on its behalf.

(b) Constituting itself into a review committee and exercising all the powers applicable therein as outlined for HRECs in this code

3. 1.2. HEALTH RESEARCH ETHICS COMMITTEE

In Nigeria, every institution, health agency and health establishment where health research is conducted is expected to establish or have access to a health research ethics committee, which must be registered with the NHREC[17].

3.1.2.1. INDEPENDENCE OF ETHICS REVIEW

For research to be ethical, it must undergo independent research. This is important for social accountability as it assures society that reasonable attempts have been made to minimize the

[17] S.34(1) National Health Bill. 2008

potential impacts of these conflicting interests[18] and ensures balanced judgements[19]. Trust, was and still is the core of ethical value and is essential in the scientific pursuit of the truth. Conflict of interest is intrinsic to the researcher's enterprise. It can lead to injury and harm to injury or harm to study, thereby damaging an entire enterprise by reducing the trust and confidence that people generally have in research. The NCHRE therefore encourages transparency through disclosure of any conflict of interest.

3.1.2.2. INDEPENDENCE OF THE HREC

The HREC is an independent body which is responsible for its decision. It must be seen to be independent. Any conflict of interest must be disclosed. It is however subject to oversight by the NHREC[20].

3.1.2.3. INDEPENDENCE OF MEMBERS

It is pertinent for the members of the REC to be independent. Consequently, no member of the REC may participate in the REC initial or continuing review of any project in which the member has a conflicting interest[21]. Conflict of interests is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgement and objectivity. It is pertinent to note that conflict of interests exists whether or not decisions are affected by a personal interest. It implies only the potential for bias.

3.1.2.4.. FUNCTIONS OF HREC

[18] Conflict of interests is a conflict between a person's private interest and his/her public obligation.

[19] Section F (e) National Code of Health Research Ethics, 2007.

[20] Sections A and C National Code for Health Research Ethics, 2007.

[21] Section D(g) National Code of Health Research Ethics, 2007; Art 19 UDBHR, 2005

The main functions of the Ethics Committee include:

a) Reviewing research proposals and protocols to ensure that research conducted will be in the spirit of endeavouring to promote health, and/or prevent disease and/or disability and cure disease;
b) Ensuring that humans involved in research are treated with dignity and that their well-being is not compromised and that animals involved in research are treated compassionately;
c) Ensuring that informed consent is obtained in the case of human subjects; and
d) Granting approval in instances where research proposals and protocols meet ethical standards;
e) Monitoring the process and evaluating the outcome of research it approves to ensure that the guiding ethical principles are adhered to throughout the research process[22].

3.1.2.5.. MEMBERSHIP OF HREC

Each HREC shall have at least 5 members and if more, then the total membership must always be an odd number[23]. The members shall be sufficiently qualified. Members should have varying academic and professional backgrounds to promote complete and adequate review of health research. It also expected that a lawyer be a member, at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas. Each HREC shall include at least one member who is not affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution[24].

[22] S.34(2) National Health Bill, 2008; Section E National Code of Health Research Ethics, 2007.
[23] Section D National Code of Health Research Ethics, 2007.
[24] Section D(c)-(f) National Code of Health Research Ethics, 2007.

3.1.2.6. JURISDICTION OF THE HREC

The authority of HREC shall be limited to the boundary of the proposing institution or the activities of its permanent members of staff, unless otherwise specified by the NHREC[25]. Where a permanent member of staff is the principal investigator of a study taking place outside the boundaries of the proposing institution, the researcher shall seek ethical oversight only from the institution in which he/she is a permanent member of staff. This provision does not preclude co-investigator(s) from seeking ethical oversight from their institution(s) where there is more than one study site[26].

3.1.2.7. INDEPENDENCE OF THE HREC MEMBERS

It is pertinent for the members of the HREC to be independent. Consequently, no member of the HREC may participate in the HREC initial or continuing review of any project in which the member has a conflicting interest[27].

3.1.2.8. DECISION MAKING PROCESS WITHIN THE HREC[28]

1.) HREC shall review prescribed application materials and have authority to approve, require modifications in (to secure approval) or disapprove all health research activities covered by this code.

[25] Section C (e) National Code of Health Research Ethics, 2007.
[26] Ibid.
[27] Section D(g) National Code of Health Research Ethics, 2007; Art 19 UDBHR, 2005
[28] Section E (d) National Code of Health Research Ethics, 2007.

2). In order for research to be approved, the decision shall ordinarily be arrived at by discussion and consensus or it shall receive the support of a simple majority of those members present at the meeting.

3). HREC may, at its own discretion, invite representations from the applicant(s), sponsor(s), institution(s) or any other person(s) that it may consider relevant to provide information pertinent to the research during the review process.

4). HREC shall notify investigator(s) in writing of its decision to approve, disapprove or require modifications of the research activity.

5). HREC shall have a maximum of 3 months from the date of receipt of a valid application to give its decision to the applicant. An application shall be considered valid only after receipt of all materials required by HREC to give a determination.

6). Where HREC considers an application of such complexity that it cannot conclude the review, the application shall be referred to NHREC and the applicant duly informed within the stipulated 3 months.

(7) Where HREC does not conclude its review in 3 months and has not referred the case to the NHREC, the applicant shall have the right to complain to NHREC with the possibility of re-allocation of the proposal to another HREC and sanction of the concerned HREC

(8) Where HREC decides to disapprove a health research activity, it shall include in its written notification, a statement of the reason(s) for its decision and give the applicant an opportunity to respond in person or in writing within 3 months of receipt of the notification.

(9) Where HREC has received representation from the applicant in response to an existing decision, HREC may decide to uphold or modify its previous decision and shall communicate this decision to the applicant within 3 months of the representation.

(10) HREC is mandated to keep all records related to its decision(s) for a minimum of 10 years after completion of the research activity.

3.1.2.9. TRANSMISSION OF THE REC DECISION

HREC shall notify investigator(s) in writing of its decision to approve, disapprove or requirement for modifications of the research activity. Where the REC fails to conclude review within the stipulated time and the application has not been referred to the NHREC, the applicant has a right to complain to the NHREC with the possibility of re-allocation of the proposal to another REC and sanction of the concerned REC[29].

3.1.3.0. ONGOING REVIEW OF RESEARCH[30]

(1) HREC shall conduct continuing oversight of research covered by this code at intervals adjudged by HREC as being appropriate to degree of risk involved in participation in the research.

(2) HREC shall have authority to examine all aspects and documents including consent forms, questionnaires, case report forms etc. that are related to the research and necessary for the HREC to conduct its oversight function.

(3) This shall be at least once a year or at least once during the lifetime of the research where the duration of the research is less than a year.

[29] Section E (d) National Code of Health Research Ethics, 2007

[30] Section E (e) (1-5) National Code of Health Research Ethics, 2007.

(4) HREC shall have authority to observe or cause to be observed on its behalf, the research and its consent process to ensure compliance with the highest scientific and ethical standards.

(5) HREC may initiate process of oversight of research in the event of receipt of complaints, information or data relevant to the research from any source.

3.1.3.1. RESPONSIBILITY OF THE HREC[31]

The HREC is to provide ethical advice to researchers in order to assist decision-making on the adequacy of proposed research projects regarding the protection of potential and actual human subjects. It must ensure that the study protocol is scientifically sound in purpose and design, methodologically rigorous, valid and feasible. It is the responsibility of the HREC to ensure human protection in all studies involving human subjects.

3.1.3.2. RELATIONSHIP WITH OTHER REGULATORY AGENCIES

The Federal Government of Nigeria acting through any of its agencies has the overall duty of protecting the welfare of citizens and residents of Nigeria. It may therefore exercise all the powers of protecting citizens participating in research[32].

3.1.3.3. HREC OVERSIGHT BODIES

There are certain agencies, who in carrying out their lawful duties exercise regulatory functions within the research environment. These include:

[31] Section E National Code for Health Research Ethics, 2007
[32] Section M National Code of Health Research Ethics, 2007.

1) Oversight of Clinical Trials by National Agency for Food and Drug Administration and Control (NAFDAC). NAFDAC is the agency responsible for registration of new finished products for sale or use as food or drugs in Nigeria. NAFDAC therefore exercises regulatory functions in the conduct of clinical trials to test efficacy and safety of such products. NHREC is responsible for ensuring that all research including clinical trials are conducted according to the highest ethical and scientific standard. Clinical trials involving new finished products in Nigeria therefore require the permission of NAFDAC and compliance with both the clinical trials guidelines issued by NAFDAC and the National Code for Health Research Ethics[33].

2) Oversight by institutions[34]: Institutions where research is conducted may elaborate guidelines for the conduct of research in accordance with their enabling law and consistent with the need for maintenance of the highest ethical and scientific standard as outlined in this code.

   Others are committees such as data safety monitoring boards, bio- safety committees, scientific committees etc.

3) Oversight by Community Advisory Committees (CAC)[35]: CAC are established by the study investigators depending on the nature of the proposed research, the research site, the study base or on the recommendation of either the institution research is based or the HREC supervising the research[36]. They are important forums for facilitating dialogue between community members, research participants and researchers. CAC members should be identified from communities where research is to be undertaken through a stakeholder

[33] Section M (a) National Code of Health Research Ethics, 2007.
[34] Section M (b) National Code of Health Research Ethics, 2007.
[35] Section M (c) National Code of Health Research Ethics, 2007.
29 Section M (c)(1) National Code of Health Research Ethics, 2007.
[36] Section M (c) (1) National Code of Health Research Ethics, 2007.

consultative process[37]. The CAC role and expectations should be clearly stated in their terms of reference. Members of the CAC may include the following:

(i) Persons with understanding of local laws, cultural values and gender issues;

(ii) Peer leaders;

(iii) Religious leaders;

(iv) Representative of the study population;

(v) Professionals who understand research or science issues;

(vi) Community leaders;

(vii) Representatives of the research team who should form no more than 20% of the membership of the CAC[38].

The primary role of a CAC is to assist investigators understand and incorporate community concerns into their research activities. This happens through different ways like relaying community concerns and problems to the community leaders, research team, institutional officials or the HREC, advising on; issues central to the informed consent process, achieving successful participants' recruitment and retention, among others[39].

The responsibilities and terms of reference for CAC may vary according to the study location, size, etc, but generally, they are to:

[37] Section M (c) (2) National Code of Health Research Ethics, 2007.
[38] Section M (c)(3) National Code of Health Research Ethics, 2007.
[39] Section M (c)(4) National Code of Health Research Ethics, 2007.

(i) provide information on traditional beliefs and needs of the study population and their concerns regarding research;

(ii) where appropriate, CAC may provide input into the design of the protocol as appropriate including the informed consent process;

(iii) advise on effective methods for disseminating information about the research and its outcomes;

(iv) provide advice and support regarding recruitment and retention of participants in the research including gender equity

(v) resolving ethical problems that may arise during the conduct of research and after the research is over[40].

4) Institutional Bio-safety Committees (IBC)[41]: Institutional Bio-safety Committees (IBC) are established by institutions that undertake research on classified hazardous substances of physical or biological nature. Any institution involved in or planning to conduct research in the classified hazardous substance is required to set up or designate a competent IBC[42]. Each IBC once formed shall consist of a bio-safety officer and at least three other officers with appropriate expertise[43]. The IBC must comply with regulations and guidelines contained in the sub-code regarding

[4040]Section M (c) (5) National Code of Health Research Ethics, 2007.
[41] Section M (d) National Code of Health Research Ethics, 2007.
[42] Section M (d)(1) National Code of Health Research Ethics, 2007.
[43] Section M (d)(2) National Code of Health Research Ethics,2007.

research on hazardous substances issued by the NHREC[44]. The IBC must be registered with the NHREC[45].

It is the responsibility of researchers to notify and provide to the IBC, the research proposal involving classified hazardous substances of physical or biological nature[46]. The IBC is expected to minimize potential human and environmental risks associated with research on or with classified hazardous substances such as pathogens, radioactive material and applications of biotechnology especially recombinant DNA techniques and processes. In order to do this, the IBC shall:

(i) Notify the NHREC of any research with hazardous substances in their Institutions;

(ii) Conduct bio-safety review of research proposals on hazardous substances;

(iii) Ensure the provision of suitable and safe storage and disposal facilities for all materials involved in work with hazardous substances;

(iv) Ensure that all appropriate technical personnel of the institution have adequate training in bio-safety;

(v) Institute a health-monitoring program for all high risk personnel involved in application, use and production of restricted categories of classified substances[47].

5) Data and Safety Monitoring Boards: A Data and Safety Monitoring Board (DSMB) is an independent group of experts established by the study sponsors to review safety data during a

[44] Section M (d)(3) National Code of Health Research Ethics, 2007.
[45] Section M (d)(4) National Code of Health Research Ethics, 2007.
[46] Section M (d)(5) National Code of Health Research Ethics, 2007.
[47] Section M (d)(6) National Code of Health Research Ethics, 2007.

clinical trial. DSMB ensures that the study is conducted and the data are handled in accordance with the provisions of the protocol and monitors adverse events and safety data[48].

Where appropriate, DSMB should be established before the commencement of the clinical trial and its membership submitted to the HREC for their record[49]. All interventional studies including drug efficacy trials, and all clinical trials should have a safety monitoring plan which will be implemented through the DSMB[50]. The membership of the DSMB should include:

(i) Individuals with appropriately training and scientific knowledge in all aspects of research;

(ii) People with adequate medical, pharmaceutical, scientific, biostatistical and/or ethics qualifications and clinical trial experience. The qualifications most appropriate for a specific DSMB will depend on the nature of the clinical trial and of the product under investigation;

(iii) At least three individuals including a clinician with competence in the research field of the trial and a statistician;

(iv) Individuals who are independent of the clinical trial and the sponsor[51].

The functions and responsibilities of DSMB include[52]:

(i) Ensure safety of study participants;

(ii) Preserve the integrity and credibility of the trial;

[48] Section M (e)(1) National Code of Health Research Ethics, 2007.
[49] Section M (e)(2) National Code of Health Research Ethics, 2007.
[50] Section M (e) (3)National Code of Health Research Ethics, 2007.
[51] Section M (e)(4) National Code of Health Research Ethics, 2007.
[52] Section M(e)(5) National Code of Health Research Ethics, 2007.

(iii) Ensure availability of definitive and reliable results in a timely manner;

(iv) Make decisions related to the safety of the study, based on the submitted results and adverse event reports on whether the study should continue or not.

The DSMB must report to the sponsor(s) of the trial, HREC and institutional officials any[53]:

(i) Concerns over differences in serious adverse events between study arms;

(ii) Serious social harms;

(iii) Concerns about the conduct of the trial;

(iv) Concerns about data integrity;

(v) Whether the study should be terminated or continued based on safety and interim data; The DSMB should determine the following before the commencement of the study[54]:

(i) Mode and time frame for receiving adverse events reports;

(ii) Frequency of receiving data;

(iii) Frequency of meetings to review the data and adverse event reports at hand. (Where there may be any element of concern, the DSMB may choose to review the data more frequently);

(iv) Channels of communication with the Principal Investigator, IRC and sponsor where necessary on decisions reached by the DSMB.

[53] Section M (e)(6) National Code of Health Research Ethics,2007.
[54] Section M(e)(7) National Code of Health Research Ethics, 2007.

3.1.3.4.. HREC COMPLIANCE AND DISCIPLINARY POWERS

The HREC has powers to recommend to the NHREC that disciplinary action be taken against researcher(s) who violates the norms, standards and guidelines set out in the National Code of Health Research Ethics, institutional guidelines, rules and regulations and the law[55].

3.2. ETHICS REVIEW CRITERIA

In carrying out its duty of ethical review, the HRECs have criteria for approval and rejection of protocols. These are in addition to the guidelines for ascertaining scientific and ethical issues relevant to the proposed study.

Nigeria is a multicultural society having over 100 tribes with over 400 languages. It is therefore pertinent for the HREC to take into account the culture and religious beliefs of the host community[56]. It should, familiarize itself with requirements and conditions of the various localities in which the research is taking place.

The impact of the research on the participants must be clear from the onset. Also to be considered in arriving at a decision are the numerous national and international legal documents guiding the conduct of research on humans[57].

Research needs to respond to community needs and national priorities, and the development of a national research agenda in developing countries must be firmly grounded in a process of priority

[55] Section N National Code of Health Research Ethics, 2007.
[56] Art 12 Universal Declaration on Bioethics and Human Rights, 2005.
[57] S. 11(b) NAFDAC GCP, 2009; Section F National Code of Health Research Ethics, 2007; Declaration of Helsinki, 2008, Belmont Report; CIOMS; International Convention on Civil and Political Right of 1966(ICCPR); Universal Declaration of Human Right (UDHR) 1948; UNESCO Universal Declaration on Bioethics and Human Rights (UDBHR), 2005.

setting[58]. It is thus imperative that reasonable means and terms of engagement be found that respond to the needs and concerns of populations[59] , in a process of participatory democracy and freedom of expression. Such a participatory process of decision-making may also enhance the prospects of achieving a fair balance in the distribution of a nation's biomedical research resources. If a country's health research system could be regarded as the ''brain'' of its health system, then ethics would constitute its ''conscience''. It is therefore imperative that such health research systems function to the highest aspirations of ethics and distributive justice.

The commentary on CIOMS guidelines 8 and 15 (9) explicitly state that ''As a general rule, the sponsoring agency should agree in advance of the research that any product developed through such research will be made reasonably available to the inhabitants of the host community or country at the completion of the successful testing. Exceptions to this general requirement should be justified and agreed to by all concerned parties before the research begins.''

3.2.1. SOCIAL VALUE OF THE RESEARCH

The research must have social value to either participants, the population they represent, the local community, the host country or the world, in order to justify the use of finite resources and risk exposure of some participants to harm. It should evaluate issues that lead to improvements in health and contribute to knowledge, contribute to capacity building, technology transfer and health

[58] Margetts B, Arab L, Nelson M, Kok F., (1999) "Who and what sets the international agenda for research and public health action?" Public Health Nutrition 1999; 2:235-6.

[59] Wilson D. (1999) North-South research in developing countries must respond to community's priorities. BMJ 1999; 319:1496-7.

care delivery strategies that address significant local health problems and add value to local participants of research, including researchers, institutions, communities and the country[60].

3.2.1.1. MEDICAL RELEVANCE OF THE RESEARCH PROJECT:

The research must be relevant both the broad health and development needs of the country and to the real needs of those who are affected by the diseases and concerns under the study. The findings of the research must be translatable into mechanisms for improving health status of Nigeria[61].

3.2.1.1.1. RELEVANCE FOR THE TARGET POPULATION

The research proposal should provide sufficient justification for the reasonable likelihood that the population on whom research is to be carried out stand to benefit from the research project and its results[62]. With regards to children, research must be in their best interest[63]

3.2.1.1.2. RELEVANCE FOR PUBLIC HEALTH

The research project must be relevant to the broad health needs of the country and to the real needs of those who are affected by the diseases and concerns of the study[64].

3.2.1.2. SAFEGUARDING INTELLECTUAL PROPERTY RIGHTS

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[60] Section F (a) National Code of Health Research Ethics, 2007; S. 17 (1), (2)(a-d), (3)(c),(d),(l) 1999 Constitution of the Federal Republic of Nigeria; Art 14 UDBHR, 2005.
[61] Section F National Code of Health Research Ethics,2007; Section 11(b)(i) NAFDAC GCP, 2009; Art 14 UDBHR, 2005.
[62] Belmont Report, 1979; Art 10 UDBHR, 2005.
[63] S.2 Child's Right Act, Cap C50 LFN 2004.
[64] Section F (a) National Code of Research Ethics, 2007; Section 2 Nuremberg Code; Art 14 UDBHR, 2005.

Nigerian law upholds and protects intellectual property rights. In order for researchers to enjoy the benefit of their work, it is important that the intellectual property rights in their work be protected, especially with respect to unpublished data, methods or results. With regards to research, the relevant intellectual property rights are in the area of copyright and patent. It illegal to infringe the intellectual property rights of others[65].

3.2.2. SCIENTIFIC VALIDITY OF THE RESEARCH

The research must have sound methodology and high probability for providing answers to the specific research question posed. The research protocol must show knowledge of the relevant literature, derived where possible from systematic review of that literature. The research methods and result should be open to peer-review and scrutiny[66].

3.2.2.1 METHOD/DESIGN OF THE RESEARCH PROJECT

The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol[67].

3.2.2.1.1. PRE-CLINICAL DATA

With regards pre-clinical data, the Copyright Act provides that literary work will be eligible for copyright if it can be shown that sufficient effort has been expended on making the work original

[65] Sections 1, 10, 12, 21 Copyright Act, Cap 28 LFN 2004; Sections 1, 2, 3, 6, 13, 17,19 Patents and Design Act, Cap P2 LFN 2004; Sections 2-6, 22 Trade Marks Act, Cap T13 LFN 2004; Sections 491-493 Criminal Code Act, Cap C38 LFN, 2004.
[66] Section F (b) National Code of Health Research Ethics, 2007; Section 6 (e) NAFDAC GCP Guidelines, 2009; Section 31 (A)(1) Code of Medical Ethics in Nigeria.
[67] Section F (b) National Code of Health Research Ethics, 2007; section 31 (A)(iii) Code of Medical Ethics in Nigeria;

in character and fixed on any medium of expression either directly or with the aid of any machine or device[68].

3.2.2.1.2 SCIENTIFIC LITERATURE REVIEW

There must be a thorough knowledge of the scientific literature, other relevant sources of information[69].

3.2.2.1.3. RESEARCH DESIGN

The research must be designed in such a way as to answer the research question and must be justifiable[70].

3.2.2.2. INVESTIGATOR'S BROCHURE

The investigator's brochure is a compilation of clinical and non-clinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects' research[71]. Its purpose is to provide the investigators and others involved in the trial with the information to facilitate their understanding of the rationale for, and their compliance with, many key features of the protocol, such as the dose, dose frequency/interval, methods of administration: and safety monitoring procedures. The IB also provides insight to support the clinical management of the study subjects during the course of the clinical trial. The information should be presented in

[68] Section 2 (a-b LFN 2004.) Copyright Act, Cap C28
[69] Para. 11, Helsinki Declaration, 2008.
[70] Section F National Code of Health Research Ethics; section 31(A) (iii) Code of Medical Ethics in Nigeria; Para. 13, Helsinki Declaration.
[71] CIOMS Guideline 1.36

a concise, simple, objective, balanced, and non-promotional form that enables a clinician, or potential investigator, to understand it and make his/her own unbiased risk-benefit assessment of the appropriateness of the proposed trial. Consequently, a medical person should participate in the editing of the investigator's brochure and its content should be approved by the disciplines that generated the data[72]. The investigator's brochure is one of the documents that guide the HREC in its decision to grant approval[73].

3.2.3. INVESTIGATOR'S QUALIFICATION

The researcher is expected to have the requisite qualification[74]. The different legislations relating to health research set out varying qualification it expects researchers in the relevant field to have[75].

3.2.4. COMPENSATION FOR DAMAGES

The researcher(s), their institution and/or sponsors must be prepared to take care of side effects and dangers to participants and remunerate them or their estates in event of death or incapacitation[76]. The essence of compensation is to restore the victim as far as possible to the position he would have been in had the incidence not occurred[77]. A research participant will only be entitled to compensation if the damage suffered is, in the eyes of the law, not too remote from the original

[72] CIOMS Guideline 7.1
[73] Section 11(b)(v) NAFDAC GCP Guidelines, 2009.
[74] S. 6(h) NAFDAC GCP Guidelines, 2009; ICH GCP Guideline 4.1.1 [E6(R1)],1966; S.15 Helsinki Declaration, 2008; S. 10 Nigerian Radiation Safety in Radiotherapy Regulation, 2006.
[75] S.S. 2(b), 12(1) Nigerian Institute of Science Laboratory Technician Act, Cap. N150; S.S. 1(a), 10 Radiographers Act, Cap R1 LFN; S.S. 1(a), 11, 12 Pharmacists Council of Nigerian Act, Cap 17 LFN; S.S. 2(a), 10 Optometrists and Dispensing Optician (Registration, etc) Act, Cap O9 LFN.
[76] Para 5.8.1 ICH Guidelines for Good Clinical Practice [E6(R1)], 1996; S.2(3)(b) Insurance Act Cap I17 LFN; Sections 3(1) and 6(1) Fatal Accidents Laws of Oyo State, Cap 161; Sections S1(iii),(iv) and 6(vi) National Code of Health Research Ethics, 2007; Section 6 (q) NAFDAC GCP Guidelines, 2009; Section 17(2)(a) 1999 Constitution; *Raimi Jenyo . v. Akinsanmi Akinreti & Anor* (1990) 4 SC 196;
[77] *Shell Petroleum Development Co. v. Farah* (1995)3NWLR (Pt 382) 148 CA. See also, *Anumbu. v. Shohet (* 1965) 2 All NLR 183

wrong. If the damage is too remote, it follows that the defendant will not be liable for such damage[78].

This compensation must however be distinguished from that due for transportation expenses or loss of income resulting from participating in the research.

3.2.4.1. COVERAGE OF DAMAGE

It is expected that provision be made for insurance and indemnity to cover the liability of the investigator and sponsor which may arise in relation to the research or trial[79]. Injuries arising from misconduct, malpractice or negligence will however not be covered by insurance and relief must be sought in either the criminal or civil courts.

S.72 of the Insurance Act[80] provides that a foreign insurer may transact insurance/reinsurance business in respect of life only where that foreign insurer is registered under the Act.

3.2.4.2 PERSONS RESPONSIBLE UNDER THE COVERAGE OF THE DAMAGE

A person whose responsibility it is to supervise a research activity stands in a fiduciary position to all who can be harmed by a breach of that duty. He therefore owes a duty of care to the latter[81]. A duty of care is owed wherever in the circumstances it is foreseeable that, if the defendant does not exercise due care, the Plaintiff will be harmed.

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[78] *Prime Merchant Bank.v.Man-Mountain Co* (2000) 6 NWLR (Pt 661) 524 CA*;* See also *Oladiti . v.Sungas Co. Ltd* (1994) 1 NWLR (Pt 321) 433 CA.

[79] S.2(3)(b) Insurance Act, Cap I17 LFN; Para 5.8.1. ICH Guidelines for Good Clinical Practice [E6(R1)], 1996;S.3(1) Fatal Accidents Laws, Cap 161 Laws of Oyo State.

[80] Cap I17 LFN 2004.

[81] Para 5.8.1. ICH Guidelines for Good Clinical Practice [E6(R1)], 1996; Sections 303-305 Criminal Code Act, Cap C38 LFN 2004.

For a cause of action to be found in negligence, there must be a duty of care owed by the defendant to the plaintiff, a breach of that duty must have occurred and damage accruing to the plaintiff as a result of that breach[82].

The standard of care expected to be exercised by the defendant is that of a reasonable man placed in the defendant's position[83].

3.2.4.3. EXTENT OF DAMAGE

This would cover all the damages resulting from the act, omission or mistake of the researcher. The nature of the damage must be foreseeable. It would include incapacitation, loss of earnings, emotional/psychological trauma. The greater the likelihood that the defendant's conduct will cause harm, the greater the amount of caution required by him[84]. Be that as it may, the seriousness of the risk created by the defendant's activity must be weighed against the importance or utility of such activity, and where the defendant's conduct has great social value, he may be justified in exposing others to risk which would not otherwise be justifiable[85]. Defences available are, contributory negligence – negligence of a person which while not being the primary cause of a tort, nevertheless combined with the act or omission of the primary defendant to cause the tort and without which the tort would not have occurred[86] and *volenti non fit injuria* - no injury is done to

[82] *Makwe .v. Nwukor [2001] CLR 7(1) SC.*.
[83] *Miss Felicia Osagiede Ojo. v. Dr Gharoro* (2006) 2 SC 105.
[84] *NW Utilities .v.Land Guarantee and Accident Co. Ltd* (1936) AC 108; *CCC Construction Co. Ltd . v. Tunde Okhai* (2003) 12 SC (Pt 1) 133.
[85] *D*avorn .v. *Bath Tramways Motors Co. Ltd* (1942) 2 All ER 333.
[86] *Appah and Anor . v. Costain (WA) Ltd and Anor* (1974) 11 SC 17.

one who consents. The implication of this is that no one can enforce a right which he has voluntarily waived or abandoned[87].

3.2.4.4. NATURE OF DAMAGE

The nature of damage depends on how it arises. It may be as a result of data and specimen collection, storage, utilization of the results, economic loss, and interference with privacy. It could be physical or psychological damage; it could be a minor or major damage having multiple effects such as burial expenses, loss of earnings, moral wrong, indignity and damage to property[88].

3.2.5. SELECTION OF RESEARCH PARTICIPANTS

The selection, recruitment, exclusion and inclusion of research participants in a research project must be just and fair, based on sound scientific and ethical principles. No person must be inappropriately or unjustly excluded on the basis of race, age, sexual orientation, disability, education, religious beliefs, pregnancy, marital status, ethnic or social origin, conscience, belief and language[89].

3.2.5.1. SELECTION CRITERIA

Ethical research must ensure fair selection of participants based on the scientific objective(s) of the research while minimizing risk. This requirement refers to both who is included and who is excluded from recruitment and the strategies employed for participants' recruitment (including choice of research sites and communities). Regardless of this requirement, participants who are at excessively increased risk of harm should be excluded. Children, pregnant women, socially,

[87] *Egbe . v. Adefaransin* (1987).
[88] SS. 3 and 6 Fatal Accidents Law, Part 2 Torts Law, Cap 161 Laws of Oyo State of Nigeria.
[89] Section F(c) National Code of Health Research Ethics, 2007; Art. 6.5 ICH Guidelines for GCP [E6(R1)], 1996.

culturally, economically, politically, educationally, physically and psychologically disadvantaged groups, groups with constrained autonomy and other vulnerable populations should not be excluded from research without explicit reasons for doing so; particularly from studies that can advance their health and well being. However specific safeguards should be included to protect the vulnerable, appropriate to degree of risk. Groups, communities, participants and researchers who bear the burden of research should share in the benefits[90].

3.2.5.1.1. INCLUSION CRITERIA

These are a set of conditions that must be met in order to participate in a clinical trial. The most important criteria used to determine appropriateness for clinical trial participation include age, sex, the type and stage of a disease, treatment history, and other medical conditions. These must be stated in the protocol and justified by the study[91].

3.2.5.1.2 EXCLUSION CRITERIA

Exclusion criteria are guidelines that identify who will not be able to participate in the trial. These vary according to the drug being tested - it can affect people who drink, smoke or exercise more than the average person, and it often affects people who have a complicated medical history. Exclusion criteria can also be based on race, age, gender and any health conditions that may be pre-existing. These must be stated in the protocol and justified by the study[92].

3.2.5.2 VULNERABLE PARTICIPANTS

[90] Section F (c) National Code of Health Research Ethics, 2007; Art. 6.5 (1) and (2) ICH Guidelines for GCP [E6(R1). 1996; Belmont Report, 1979; Sections 17(2) & 42 1999 Constitution.
[91] Item 10, Appendix 1 CIOMS
[92] Item 10, Appendix 1 CIOMS Item 10, Appendix 1 CIOMS

Research with vulnerable populations should only be undertaken when it is directly related to their own health and these studies cannot be done with other groups. Consequently their inclusion must be justified. The researcher is also under an obligation to protect their rights and welfare[93].

Vulnerable participants include children, women, prisoners, the illiterate[94] and people with limited resources, refugee population and internally displaced persons.

3.2.5.2.1. POPULATION OR COMMUNITIES WITH LIMITED RESOURCES

Research involving low income communities, must be geared at their health needs and the priorities of the population or community in which it is to be carried out. The benefits of the outcome of the study must be available for the population or community[95].

3.2.5.2.2. COMMUNITIES/COUNTRIES WITH INSUFFICIENTLY WELL-DEVELOPED SYSTEMS FOR THE PROTECTION OF THE RIGHT AND WELFARE OF RESEARCH PARTICIPANTS

As with study participants in developing countries, most human research participants in Nigeria are unaware of their rights, thereby making them vulnerable. It is therefore pertinent for researchers and sponsors to ensure adequate and comprehensive consent documents. This will give the subject the opportunity of understanding the essence of the study and their rights, duties and obligations with respect to the study among other things[96].

[93] Section F (c) National Code of Health Research Ethics, 2007; CIOMS Ethical Guidelines 13-16; Art 8 UDBHR, 2005; Section 16 Child's Right Act, Cap C50 LFN.
[94] Illiterates Protection Law, Cap 61 Laws of Oyo State of Nigeria.
[95] Art 10 CIOMS Ethical Guidelines, 2002; Belmont Report.
[96] Section F (5) (f) National Code of Health Research Ethics, 2007; section (6)(i) NAFDAC GCP Guidelines, 2009; Art n10 CIOMS Ethical Guidelines; S. 17(2)(a)&(d) , S.S. 38&39 1999 Constitution, 1999.

3.2.5.2.3. INDIVIDUALS WITH LIMITED CAPACITY OR FREEDOM TO CONSENT OR TO DECLINE TO CONSENT

With regards to the above mentioned group of people, strict adherence to ethical principles is required. The means of protecting their rights must be apparent and complied with[97]. Additional safeguards must be put in place so as to reduce potential for exploitation.

3.2.5.2.4. JUNIOR OR SUBORDINATE MEMBERS OF A HIERARCHICAL GROUP

For research on medical students, soldiers, employees of the sponsor to be ethical, they must have given a valid informed consent. Failure to do this gives an impression of the existence of undue influence[98]. The effect of undue influence on a contract is that it renders it illegal and therefore null and void[99]. Consequently, the informed consent should be obtained by a well-informed physician who is not engaged in the study and completely independent[100].

3.2.5.2.5. PERSONS WHO HAVE SERIOUS DISEASE

Persons with serious diseases or illness or who are unconscious come within the class of people who are vulnerable. In view of the fact that they are incapacitated and unable to give informed legal consent, care must therefore be taken in recruiting them for research[101].

3.2.5.3. RECRUITMENT PROCESS

[97] Section 10 NAFDAC GCP Guidelines, 2009; Sections 13 & 15 CIOMS Ethical Guidelines; Art 7 UDBHR, 2005.
[98] Section F(c) National Code of Health Research Ethics, 2007; CIOMS Guideline No. 13; Para 23, Helsinki Declaration; *Pan Builder (Nigeria) Ltd . v. First Bank of Nigeria Ltd* (2000) 1 NWLR (Pt 642) 684.
[99] *Bua. v.Bashir Dauda* (2003) 6 SC (Pt II) 120.
[100] Para 23 Helsinki Declaration.
[101] Section 10 NAFDAC GCP Guidelines, 2009; CIOMS Guideline No. 13; Belmont Report.

The law provides that the researcher must state in the protocol his/her proposed method of recruiting research participants, showing justification for his proposed choice[102].

3.2.5.3.1. RECRUITMENT PROCESS IN GENERAL

The researcher must be a suitably qualified individual. The investigator's competence is assessed by technical competence. Technical competence, which includes research competence, is assessed by education, knowledge, certification and experience. There must be no evidence of inducement and pressure[103].

3.2.5.3.2. RECRUITMENT PROCESS BY ADVERTISEMENT

Nigerian law does not prohibit recruitment of research participants through advertisement. The potential researcher must however have the requisite qualification. However, the Tobacco Smoking (Control) Act[104], which was enacted pursuant to the WHO Tobacco Treaty 2005, placed a restriction on advertising tobacco products in a bid to encourage smoking. It is presumed that advertising for tobacco research will fall under this provision. It is expected that the potential researcher will have the requisite qualification.

3.2.5.4. COMMUNITY ASSENT

[102] S.11(b)(xi) NAFDAC GCP Guidelines, 2009;
[103] Section 11 (b) (iv) NAFDAC GCP Guidelines, 2009.
[104] Cap T6 LFN .

In certain instances, community consultation or assent may have to precede research activities in order to engender community buy-in and to respect the socio-cultural values of the community and its institutions. It may also be necessary to inform the community from time to time about the progress of the research, pertinent findings that may influence their health and well being, and the outcome of the research[105]. This however does not preclude obtaining individual consent.

The definition of community varies with research and is based on application of the best scientific principles[106].

3.2.6. INFORMED CONSENT

The Nuremberg Code, written in the aftermath of the atrocities perpetrated by Nazi doctors, during the Second World War, makes the voluntary consent of the human research participant "absolutely essential"[107]. However, in 1964 the World Medical Association, in the Declaration of Helsinki, took a different stance, allowing research on human beings without the capacity to consent, if consent can be obtained from a legally authorised representative.

Consequently, no investigator should conduct a research involving humans unless he has obtained the informed consent of the participants or their legal/authorized representative. Informed consent must be obtained under circumstances that provide the prospective participant or their

[105] Section F (f) (13)(g) National Code of Health Research Ethics, 2007; Art. 22 Helsinki Declaration.
[106] Section E (s)(4)(iv) National Code of Health Research Ethics, 2007._
[107] "Directive for Human Experimentation". Retrieved from http://ohsr.od.nih.gov/guidelines/nurembergtrial, on 22nd Nov, 2010.

representative sufficient opportunity to consider whether or not to participate and the circumstances shall minimize the possibility of coercion or undue influence[108]. The legal justification for informed consent in Nigeria is founded on three areas of the law, namely, contract, torts and the Constitution.

There is a contractual relationship between the researcher and participants. Generally, for a contractual relationship to exist, the elements of contract such as offer, acceptance, consideration and intention to enter into a legal relationship must be present. The offer takes place when the researcher approaches prospective research participants to take part in the research project. This offer may or may not be accepted by the prospective research participants. Where the recruitment process is carried out by advertisement, the advert will be an invitation to treat. In such a case, the participant makes the offer which the researcher accepts on recruitment.

Consideration is an essential element for the formation of a contract. It may consist of a promise to perform a desired act or a promise to refrain from doing an act that one is legally entitled to do. It can take the form of money, physical objects, services, promised actions, abstinence from a future action. In this instance, the consideration would consist of whatever the researcher promises to do in return for securing participation in the research.

Where the participants agree to go ahead with the procedure, it is presumed that there is an intention to create a legal relationship which can be terminated at the instance of either party.

With regards to the law of Torts, the law of battery and negligence apply.

[108] Sections 17(2), 34, 38, 1999 Constitution; Section 7(1) Child's Right Act, Cap C50 LFN; Sections. E(s)(1)(i) , F(f)(1-13) National Code of Health Research Ethics, 2007; Sections 4, 6(i) NAFDAC GCP Guidelines, 2009; Part C (1) Belmont Report; Art. 6 UDBHR; Art. 18 ICCPR; ICH GCP Guideline 6.5(1)&(2) [E6(R1)]; CIOMS Guidelines 5,6&9; NIMR IRB Guidelines.

Battery involves touching without the consent of the victim, consequently, treatment of the victim without his consent is an actionable wrong. It protects the individual's bodily integrity. In addition, good faith on the part of the offender is not relevant[109].

Negligence on its part requires a legally established duty from the defendant to the plaintiff, which the former must have breached. The plaintiff must experience an injury which is measurable in monetary terms called damages. Such injury must be causally related to the defendant's breach of duty. Lastly, the causal relationship between the act or omission and the injury must be proximate[110].

3.2.6.1. CAPACITY

For informed consent to be legal and acceptable, study participants must possess the ability to comprehend information provided concerning the research. Consequently, participants must be legally capable of granting consent.

3.2.6.1.1. ADULT

Under Nigerian law, a child is anyone under the age of 18years[111]. We can therefore safely assume that all persons 18years and above are adults and *prima facie* capable of granting a legally enforceable consent to research. In some cultures however, families and groups participate in

[109] *Dr Rom Okekearu. v.Danjuma Tanko* (2002) 9-10 SC 101.
[110] *Basinco .v. Woermann Line* (2009) 13 NWLR 149 (SC).
[111] 1999 Constitution; Child's Right Act Cap C50 LFN 2004; see also the Children and Young Persons Laws of the various states of the Federation.

decision making. In certain situations, others such as the family head or husband actually take decisions instead of the adult participants.

3.2.6.1.2 CAPABLE ADULT

Once a person is considered an adult and of sane mind, he is capable of granting a legal binding consent. In some cultures however, families and groups participate in decision making. In certain situations, others such as the family head or husband actually take decisions instead of the adult participants[112].

With regards to illiterates, the fact that an individual is an illiterate does not preclude him from being legally capable of granting consent. The Nigeria law requires that the consent form/document be first read over and explained to illiterate person prior to consent being obtained, and a statement that the signature or mark was made by such person. This is known as the **Illiterate Jurat**. Where such document does not contain the **Illiterate Jurat** or its content is false, the writer of the document shall be guilty of an offence and liable on conviction to a fine of one hundred naira or to imprisonment for six months[113]

3.2.6.1.3. INCAPABLE ADULT

A person who has attained the age of majority may be incapable of making rational decision due to illness, insanity, incarceration or intimidation. Such an individual will not be able to give valid

[112] Nuremberg Code.
[113] Sections 3(b) and 4 Illiterate Protection Law, Cap 61 Laws of Oyo State of Nigeria.

consent and a legal representative would be required to grant consent on his behalf[114]. This would usually be the husband or the family head as the case may be.

3.2.6.1.4. LEGAL REPRESENTATIVE/PROXY

A legal representative is any person vested with such powers by the law to protect the interest of people who may be vulnerable for various reasons. These may be parents or guardians. They may be family members, lawyers, social workers or respected community or religious leaders, who are appointed by the incapable adult, or other members of the family or the government/court, known as the guardian *ad litem*. In granting such consent, the best interest of the person being represented must be the basis of granting consent[115].

3.2.6.1.5. MINORS

The Child's Right Act defines a minor/a child as any person who has not attained the age of 18 years[116]. A minor is regarded as not having the capability to make rational decisions and consequently vulnerable[117]. In Nigeria, various laws govern issues involving minors. These include the Child's Right Act[118], Criminal Procedure Act[119], Criminal Code Act[120], the Children

[114] Section 10 NAFDAC GCP Guidelines, 2009; Art 5 and Art 7(a) UDBHR; CIOMS Guidelines 9 & 13.
[115] Section 17(2) 1999 Constitution; Section 10(a) NAFDAC GCP Guidelines, 2009; Section 2 Child's Right Act, Cap C50 LFN; Para 26 Helsinki Declaration.
[116] Section 27(7) Child's Right Act, Cap C50 LFN.
[117] Art 5&7 UDBHR; Para 25 Helsinki Declaration; Section 9 NAFDAC GCP Guidelines, 2009.
[118] Cap C50 LFN.
[119] Cap C41 LFN.
[120] Cap C38 LFN.

and Young Persons Law of the various States of the Federation and the African Charter on Human and Peoples' Right (Ratification and Enforcement) Act[121].

3.2.6.1.6. CAPABLE MINOR

A capable minor is anyone who has not attained the age of 18 years, but is capable of testifying, making rational decisions, and doing things for the purposes of enhancing his/her welfare[122].

To ascertain the mental stability of a minor, it would be necessary to assess his/her socio-psychological well-being. To determine this, the minor's ability to understand the information given at the material time, giving him/her the ability to decide whether or not to participate is crucial. Where however, there is a doubt as to the minor's ability to make an independent judgment, consent from a legal representative would be advisable[123].

3.2.6.1.7. INCAPABLE MINOR

A minor will be regarded as being incapable of giving valid consent where factors such as infancy, illness, mental incapacity and socio-cultural and religious norms arise[124]. In such instances, the HREC would be expected to critically review the research protocol so as to guarantee the presence

[121] Cap A9 LFN.
[122] Minors who are 7years and above can be criminally responsible-S.30 Criminal Code Act, Cap C38 LFN; 12year olds and above may be criminally responsible for omissions- S.30 Criminal Code Act; 12-16 year olds can enter into contracts of apprenticeship-S.49 Labour Act, Cap L1 LFN.
[123] Section 9 (d) NAFDAC GCP Guidelines, 2009; Child's Right Act, Cap C50 LFN; Section 17(2) 1999 Constitution; CIOMS Guidelines 13 and 14.
[124] In some cultural and religious settings, children are 'seen but not heard'.

of safeguards for the best interest of the child to be served. In addition, the best interest of the minor should be considered in requesting for consent from parents or guardian of the minor[125].

3.2.6.1.8. LEGAL REPRESENTATIVE

A legal representative is a person appointed by law to safeguard the protection of anyone regarded as being vulnerable and therefore incapable of taking reasonable decisions. This may be a parent or guardian of the latter.[126]

3.2.6.2 PARTICIPANTS' RIGHT TO INFORMATION

An individual's right to information is a fundamental human right guaranteed under sections 38 and 39(1) of the 1999 Constitution of the Federal Republic of Nigeria. With regards to obtaining informed consent for human research purposes, the information given must be material information necessary for the prospective research participant to decide whether or not he will participate in the study. The right to receive information concerning the study is continuous and extends even to the period after the study has been concluded[127]. Research participants are entitled to retain a copy of the consent form[128].

3.2.6.2.1. FORM OF THE INFORMATION

[125] Section 9(9) NAFDAC GCP Guidelines, 2009; Sections 19&20 Child's Right Act; Art 12 UDBHR; CIOMS Guidelines 9, 13, 14; Paras. 27 &28 Helsinki Declaration of 2008.
[126] Sections 7 (2-4), 14 Child's Right Act.
[127] Section F (f)(7) National Code of Health Research Ethics, 2007; S.6(d) NAFDAC GCP Guidelines, 2009; NIMR IRB Guidelines; Section 19(b) Code of Medical Ethics in Nigeria.
[128] Section F (f) (6) National Code of Health Research Ethics, 2007

The consent document should be written in lay language, that is, at the educational level not higher than that of individuals with at most 9 years of education in Nigeria[129]. Where the research participants do not understand English language, the consent document must be translated to the relevant language of the participants[130]. The informed consent document may not include any exculpatory language through which the participant or their representative is made to waive or appear to waive any of their legal rights, or release or appear to release the investigator, sponsor, institution or its agents from liability of negligence[131].

3.2.6.2.2. SCOPE OF THE INFORMATION

The information given should contain all facts material for the participant to arrive at an informed decision. It should state details of the purpose and nature of the study; identity of the researchers, duration, estimated risks and benefits and appropriate alternatives, possible benefits to participants, researchers and others, funding, mechanisms to protect confidentiality within the confines of what is possible and the law, what would be done with the results, who to contact if there are questions[132].

3.2.6.3. FREEDOM OF CONSENT

[129] Section F (5)(f)(1) National Code of Health Research Ethics, 2007.
[130] NIMR IRB Guidelines
[131] Section 4 NAFDAC GCP Guidelines, 2009.
[132] Section F (f) National Code of Health Research Ethics, 2007; section 4 NAFDAC GCP Guidelines, 2009; NIMR IRB Guidelines; sections 17 (2)(a) and 39(1) 1999 Constitution.

Consent should not be obtained under duress and coercion. The participants must be made to realise that consent should be freely given and may be withdrawn at any time during or before the study is concluded[133].

3.2.6.3.1. COMPENSATION TO SUBJECTS

Consent must be freely and seen to be given freely. Incentives given should not constitute coercion by being too tempting for the people to risk the study without appropriately considering the risks and the benefits of the study[134].

3.2.6.4. FORM OF CONSENT

Informed consent, whether granted by the participants themselves or by their representatives, may be written or oral in certain circumstances. The contents of the informed consent document must be approved by the HREC[135].

3.2.7 RISK TO BENEFIT RATIO

Before the trial is initiated, foreseeable risks and inconveniences must be weighed against the anticipated benefit for the individual trial participant and other present and future patients. A trial will be continued only if anticipated benefits justify the risks. The risks and benefits should be

[133] Sections 4 and 6(1) NAFDAC GCP Guidelines, 2009.
[134] Sections 9 (c), 10 (d) NAFDAC GCP Guidelines, 2009; NIMR IRB Guidelines; CIOMS Guideline 7.
[135] Section F(f) National Code of Health Research Ethics, 2007; Section 4 NAFDAC GCP Guidelines, 2009; NIMR IRB Guidelines; ICH GCP Guidelines 4&8 [E6(R1)].

considered at the level of individual research participants and at the level of the community, whenever appropriate[136].

3.2.7.1. RISKS OF THE RESEARCH

All bio-medical researches involve risks. There must be valid attempts to minimize risks and maximize health related benefits. Special consideration should be given to the rights of individual participants, communities and the researchers as well to ensure that their dignity and other human rights are respected throughout the research process[137].

3.2.7.1.1 HARM

Harm associated with research can include loss of life, physical injury or psychological injury. These can be ascertained by their nature and their extent. In planning the research these must be taken into account. The assessment of risks requires a careful array of relevant data, including alternative ways of obtaining the benefits sought in the research. Adequate provisions must be made to compensate participants in case harm occurs[138]. The risk-knowledge calculus must be applied to ensure that risks are reasonably compared to the knowledge to be gained[139].

3.2.7.1.2. NATURE OF HARM

[136] Section 6(b) NAFDAC GCP Guidelines, 2009; section F (d)(3) National Code of Health Research Ethics, 2007; NIMR IRB Guidelines; Part B (2) and Part C (2) Belmont Report; CIOMS Guidelines 8 and 12; Paras 16,17,20, 22 and 23 Declaration of Helsinki; Art 4 UDBHR.
[137] Section F(d) National Code of Health Research Ethics, 2007; Section 6 (c) NAFDAC GCP Guidelines, 2009; Section 17(2) 1999 Constitution.
[138] Section F (d National Code of Health Research Ethics, 2007; sections 3 and 6 Fatal Accidents Law, Cap. F1 Laws of Lagos State, Nigeria.
[139] Section F (d) National Code of Health Research Ethics, 2007;Part B(2) Belmont Report; Section 17(2) 1999 Constitution.

The requirement that research be justified on the basis of a favourable risk/benefit assessment bears a close relation to the principle of beneficience, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons. The term "risk" refers to a possibility that harm may occur. Risk whether small or high, refer both to the probability of experiencing a harm and the severity of the envisioned harm[140].

3.2.7.1.3 EXTENT OF HARM

The extent of possible harm in research varies from minimal to significant. Risk of research may affect the individual subjects, their families, and the society at large[141].

3.2.7.1.4. MEASURE TO MINIMIZE RISKS

The researcher must take necessary steps to minimize the risks associated with the research. These include monitoring the subjects and provision of medical care delivered by qualified health care providers[142].

3.2.7.1.5 MONITORING

HREC conducts continuing oversight of research covered by this code at intervals adjudged by HREC as being appropriate to degree of risk involved in participation in the research.

HREC has authority to examine all aspects and documents including consent forms, questionnaires, case report forms etc. that are related to the research and necessary for the HREC

[140] Part C(2) Belmont Report.
[141] Part C (2) Belmont Report.
[142] Section 6(g) NAFDAC GCP Guidelines, 2009; NIMR IRB Guidelines; Section E (s) (6) (iii) National Code of Health Research Ethics, 2007.

to conduct its oversight function. This should be at least once a year or at least once during the lifetime of the research where the duration of the research is less than a year.

HREC has the authority to observe or cause to be observed on its behalf, the research and its consent process to ensure compliance with the highest scientific and ethical standards. HREC may initiate process of oversight of research in the event of receipt of complaints, information or data relevant to the research from any source[143].

3.2.7.1.6. QUALITY ASSURANCE

The investigator and sponsor are responsible for implementing and maintaining quality assurance and quality control systems in line with the requirements of the law.

The investigator is responsible for the documentation of all steps in data management to allow step-by-step retrospective assessment of the quality of the data and the performance of the research[144]. Data must be retained by the HREC for 10 years, following the completion of the research[145].

An investigator should retain records required to be maintained under this section for a period of 5 years following the date a marketing application is approved for the medicinal product for the application is not approved for such indication, until 5 years after the investigation is discontinued and NAFDAC is notified[146]

3.2.7.1.7. APPROPRIATE RESOURCES

[143] Section E (e) (1-5) National Code of Health Research Ethics, 2007; ICH GCP Guidelines 5.18.1(a) &(c).
[144] Section E (s) (6)(vii) National Code of Health Research Ethics, 2007;Sections 6(m) and 16 NAFDAC GCP Guidelines, 2009; ICH GCP Guidelines 5.1.1 and 5.1.3 [E6(R1)].
[145] Section E (d) (10) National Code of Health Research Ethics, 2007.
[146] Section 23 NAFDAC GCP Guidelines, 2009.

The researcher must provide suitable infrastructure and means for the study to be carried out. His ability to undertake the study must be obvious and the must be evidence that the research team is adequate and competent[147].

3.2.7.1.8. COMPETENT PERSONNEL

The study must be conducted by suitably qualified individuals. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s)[148].

3.2.7.2 BENEFITS OF RESEARCH

The study should impact positively on the life style of the participants.

Research should evaluate issues that lead to improvements in health and contribute to meaningful knowledge. Such knowledge should be disseminated to all relevant stakeholders during and after the conduct of research. In certain instances, for example in some international collaborative studies, research should be integrated with comprehensive capacity building, technology transfer and health care delivery strategies that address significant local health problems and add value to local participants of research, including researchers, institutions, communities and the country[149].

3.2.7.2.1. DIRECT BENEFITS

[147] Sections 6 (m) and 8(b) & (c) NAFDAC GCP Guidelines, 2009; ICH GCP Guidelines 4.2.1 and 4.2.3 [E6(R1)].
[148] Section 6(h) NAFDAC GCP Guidelines, 2009.
[149] Section F (a) National Code of Health Research Ethics, 2007.

These are benefits which flow directly to the participants. These include capacity building, access to scientific and technological knowledge, special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research[150].

3.2.7.2.2. INDIRECT BENEFITS

These are those benefits which are not directly enjoyed by the participants but indirectly benefit him, his community or posterity. An example is the provision of new diagnostic and therapeutic modalities or product stemming from the research.

3.2.7.2.3. MINIMAL RISKS

This refers to the probability of experiencing harm and the severity of the envisaged harm[151]. It means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical and psychological examinations or tests and where confidentiality is adequately protected.

3.2.7.2.4. UPPER THRESHOLD OF RISK

The assessment of risks and benefits requires a careful evaluation of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. This will assist the

[150] Section F (a) National Code of Health Research Ethics, 2007; Art 15 UDBHR.
[151] Part C(2) Belmont Report.

determination whether or not to participate. The upper threshold of risk refers to the chances of the risk occurring and its magnitude[152].

3.2.8 CONFLICT OF INTEREST

The risk of conflict of interest in research involving humans is the adverse effect it has on the quality of research, with the probability that commercially funded studies will support their sponsors' product. This may possibly harm human subjects and anyone who relies on the research, including patients[153].

A researcher must therefore disclose the sources and extent of funding for the research to the research participants and the ethics committee and where appropriate the regulatory, authority, and must declare any affiliation or financial interest at the time of proposing and reporting the research.

Any employment or any other relationships (including stock ownership, receipt of grants, honoraria or support from potential research sponsors) that may be construed as conflict of interest within the context of membership of the HREC[154].

3.2.9 PROTECTION OF PRIVACY AND CONFIDENTIALITY

Participants' right to privacy and confidentiality must be protected. The researcher must ensure that where personal information about research participants or a community are collected, stored, used or destroyed, it should be done in ways that respect the privacy or confidentiality of the

[152] Part C (2) Belmont Report.
[153] An example of this is the death of Jesse Gelsinger in the Univ. of Pennsylvania gene therapy trial.
[154] Section C (b)(1)(v) National Code of Health Research Ethics, 2007.

participants or the community and any agreements made with the participants or community. Except in situations when information is available in public domain, all information and records provided by participants and/or obtained indirectly, on the participants/patients must be kept confidential[155].

Release of any identifying information may only be done as required by law and/or with the expressed permission of the participants/patients[156].

3.2.9.1 PRIVACY

Privacy is concerned with access to personal records. The right to privacy is a right guaranteed by the Constitution of the Federal Republic of Nigeria[157].

3.2.9.2. PROFESSIONAL SECRECY

The Code of Medical Ethics in Nigeria places the physician in a fiduciary position with the patient. The same is the case for researchers and participants. It therefore expected that the researcher would ensure that strict confidentiality of participants/patients private information is maintained.

3.2.9.3. DATA PROTECTION

There are no specific data protection legislation in Nigeria. Be that as it may, ethical principles put the onus on the researcher to engage qualified staff to handle and verify data.[158]

[155] Section 37 1999 Constitution; Section F (f) (13) (g) National Code of Health Research Ethics. 2007; Sections 6(l) & 7 (p) NAFDAC GCP Guidelines, 2009; CIOMS Ethical Guideline 18; Art 9 UDBHR; Para 21 Helsinki Declaration; Sections 8 & 205(2) Child's Right Act, Cap C50 LFN.
[156] Civil Procedure Rules of the various states.
[157] Section 37 1999 Constitution.
[158] Section E (s) (6) (vii) National Code of Health Research Ethics, 2007; ICH GCP Guideline 5 [E6(R1)].

3.2.9.4 RIGHT OF ACCESS TO DATA

The study participants have a right to access any data collected on them pursuant to the study. Other individuals may by virtue of provisions of law have rights of access to data on research participants. These rights are however subject to provision on privacy and confidentiality[159].

3.2.10. ONGOING RESPECT FOR RESEARCH PARTICIPANTS

For research to be ethical there must be respect for potential and enrolled participants. This implies that potential participants be treated with respect from the moment that they are approached to the conclusion of the research should they choose to participate. Their right to privacy may not be needlessly compromised. Participants must know that their involvement is voluntary and that they can withdraw at any time without penalties. However, data, samples, etc. already contributed to the research up to that point may not needlessly be withdrawn as this may jeopardise the scientific validity of the research, be unjust to those who remain in the study as all or part of their sample or data may have been used or modified into different form(s), including presentation at meetings or publications by the researchers. Respect entails that participants must be treated as partners in the research enterprise with every opportunity taken to inform them of the progress of the research and any new finding that may have potential impact on their health and well being, and on their continued participation in the research. It also entails protection of the welfare of research participants. This means that the process of research must be carefully monitored to ensure that participants are not exposed to excessive risk and all adverse events are examined in detail and promptly. Such adverse events must also be reported to HREC and efforts made to prevent future

[159] Section 39 1999 Constitution.

occurrences. Full medical care must be provided to participants who have suffered such adverse events and where warranted compensations paid.

The requirement to respect both enrolled and potential participants means that researchers should engage with communities where research is being conducted whenever this is appropriate. In certain instances, community consultation or assent may have to precede research activities in order to engender community buy-in and to respect the socio-cultural values of the community and its institutions. It may also be necessary to inform the community from time to time about the progress of the research, pertinent findings that may influence their health and well being, and the outcome of the research[160].

3.2.10.1. DURING THE RESEARCH

It is the researcher's duty to monitor research participants while the research is on-going. This includes promptly reporting adverse events; the appropriate management of such events and post-trial follow up. This includes pre and post trial counselling[161].

3.2.10.2. AFTER THE RESEARCH

It important to ensure that participants' well- being are not affected by ending their participation. They have the right to protection against any harm they would suffer as result of participating in the study. This could be medical or even socio-political retaliation.

The investigator must provide adequate and safe medical or dental care, where appropriate, to participants during the research, within the expertise of the investigator, and must ensure that

[160] Section F (f)(13)(g) National Code of Health Research Ethics, 2007.
[161] Section E (s) (ii) National Code of Health Research Ethics, 2007; Sections 6 (g), 32, 33 NAFDAC GCP Guidelines, 2009.

appropriate medical care and follow-up procedures are maintained after the research for a period of time that is dependent upon the nature of the disease, the research, and the intervention(s). The investigator must provide assurances that reasonable efforts shall be made to ensure that the benefits of research is made available to the community where the research was conducted. Details of any arrangement to ensure this shall be worked out by the researchers, sponsors, HREC, community leaders and Community Advisory Committees[162].

[162] Section E (s) (iii-iv) National Code of Health Research Ethics, 2007.

CHAPTER 4

RIGHTS AND RESPONSIBILITIES OF RESEARCHERS AND INSTITUTION[1]

4.1. Relationships between researchers and institutions:

The institutions should protect researchers from undue pressure to compromise established ethical standards in the execution of studies. Institutions have a responsibility to take appropriate steps to protect researchers against pressure inimical to the observance of the ethical guidelines for research in spite of the urge and necessity to carry out research and make money. Culture sensitive issues of research sites should not be sacrificed on the altar of research and development[2].

4.2. Protection and promotion of integrity in research

Researchers have a right and responsibility to refuse to continue to undertake studies that contravene ethical guidelines, violate the integrity of research and/or compromise their individual autonomy in all stages of research including design right through to implementation and publication stages if their rights are being violated[3].

4.3. Relationship among researchers

Research assistants, students and co-investigators are subject to the same rules as the principal investigators. They are required to promote, protect and be sensitive to the interests of study participants and the principal investigators are responsible for the conduct of their employees.

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[1] Sections 19-27, 32 NAFDAC GCP Guidelines, 2009; Section E (s) National Code of Health Research Ethics, 2007.
[2] Section E (s) (5) National Code of Health Research Ethics, 2007.
[3] Section E (s) (3) National Code of Health Research Ethics, 2007.

The research staff should be adequately trained and should not be given functions that are beyond their educational level.

4.4. Data sharing, reporting and publication of research results[4]

Except otherwise agreed, the researcher, institutions and sponsors have joint ownership of data. Personal identifiers must however be removed before data is shared with other researchers. Data that could positively impart the lives of research participants should be released without delay.

All recommended reports and findings should be filed as soon as they are available whether or not they support the expected outcome(s). Appropriate credit should be given to data or information obtained from another source. It is unethical for a researcher to disseminate information from a study that has not been peer reviewed.

4.5. Rights and responsibilities of Peer reviewers/referees

Peer reviewers have an ethical duty to undertake the duty objectively, impartially and constructively. There must be disclosure of actual or potential personal or professional conflicts of interest with any of the material for review. Plagiarism is unethical and should therefore be avoided. Where a reviewer discovers malpractice or a violation of ethical principles he has an obligation to report to the appropriate authority.

[4] Section E (s)(2) National Code of Health Research Ethics, 2007.

4.6 Rights and responsibilities of Funders and Sponsors[5]

The funders and sponsors are responsible for ensuring that the study complies with ethical standards. They must insist on written authorization from appropriately constituted ethical review committee.

They should maintain adequate records showing receipt, shipment, or other disposition of the investigational medicinal products. They are expected to maintain complete and accurate records showing all financial interests of investigators.

The sponsors shall ensure the return of all unused supplies of the investigational medicinal product on conclusion or termination of the study.

[5] Sections 16-18 NAFDAC GCP Guidelines, 2009. See also Section 13 of the Corrupt Practices and other Related Offences Act, Cap C31 LFN, which makes it an offence for anyone including sponsors of research to give or offer public officers gratification for their services.

CONCLUSION

The word "ethics" derives from the Greek "ethos" which means custom or character. It can be contrasted with morality, which frequently relates to how one was raised and what values one learnt from parents, religion, culture and other influences. Ethics has helped to shape regulations, though it goes beyond what regulations require to include what we ought to do.

Research for health has been defined as the generation of knowledge that can be used to promote, monitor or conduct surveillance of health of populations. Health research is the systematic generation of new knowledge in the field of medical, natural, social, economic and behavioural science and its use to improve the health of individuals or groups[1].

This work has provided an indepth analysis of the Nigerian legal system with a view of establishing the laws relevant to research involving humans. . It discussed the Nigerian Legal System as it relates to human subject research. The legal basis for research ethics governance was discussed in line with the principles of autonomy, beneficence and justice. These principles were, for the purposes of the study sub divided into subheads which can be grouped as follows:

- Independent Review: the importance of this cannot be over emphasized. Review by individuals not affiliated with the clinical research helps minimize the potential impact of conflicts of interests. It gives assurance that the trial has been ethically designed. Consequently, the risk-benefit ratio will be favourable.
- Value: Research that is ethical must be valuable in the sense that it would lead to improvements in the lives and well-being of the research subjects. It must also generate important knowledge.

[1] *The National Strategic Health Development Plan Framework.*, (2nd Draft) by the TWG-NSHDP/Health Sector Development Team.

- Scientific Validity: The research design must show that the method to be used is valid and practically feasible. It must have a clear scientific objective, must be designed using acceptable principles, methods and reliable practices. It must possess sufficient power to definitively test its objectives and declare a plausible data analysis plan.
- Favourable risk-benefit ratio: For a research to be ethical, the risk-benefit ratio must be favourable in the sense that the potential risks to individual subjects are minimized; the potential benefits to individual subjects are enhanced and the potential benefits to individual subjects and society are proportionate to or outweigh the risks.
- Informed Consent; This is based on the requirement of respect to persons and their autonomous decisions. This study recognized the different decision making process as it relates to cultural practices of Nigerians.
- Subject selection: This must be fair and guided by the scientific aims of the research and justified by the principles that equals should be treated similarly and that both the benefits and burdens generated by social co-operation and activities such as clinical research should be distributed fairly.
- Respect for potential and enrolled subjects- this is in relation to treating the research participants with respect throughout their participation in the research and even after their participation is terminated.

The project highlighted the aspects of research ethics such as review criteria and the role and responsibility of ethics review committees. The rights and responsibilities of researchers and institutions were enumerated. Undue influence was however not discussed specifically. This is because, undue influence is evident in other areas discussed such as research involving subordinates or vulnerable population.

The pre-2006 era was examined to lay the foundation for the post-2006 era. The inadequacy[2] of the existing regime of research ethics governance which characterized the pre-2006 era was brought to the limelight by the Pfizer incidence in Kano.

The Pfizer incidence involved a particularly controversial drug trial which was run by Pfizer in the Kano following an outbreak of an epidermic of meningitis in 1996. The research participants were children and the study compared a new drug developed by Pfizer called Trovafloxacin (TROVAN) with the gold standard drug Ceftriaxone. The experiment raised a number of ethical issues. These included:

- The allegation that children in the control group were given a low dose of Ceftriaxone in order to produce evidence of the efficacy of TROVAN.
- The parents of the children in the study did not provide informed consent on behalf of their children, as many could not speak English.
- Parents expected that their children would be receiving treatment instead of participating as research subjects.
- There was no ethical review conducted by Nigerian authorities, as there was not Research Ethics Board in existence at the hospital where the trial was carried out.

[2] It has been observed that the oversight of research involving human subjects is widely believed to be inadequate. See "Responsible Research: A Systems Approach to Protecting Research Participants"., Washington, DC: Institute of Medicine: 2002. Referred to in Ezekiel J Emmanuel, et al: "Oversight of Human Participants Research: Identifying Problems to Evaluate Reform Proposals"., American International Med. 2004; 141: 282-291.

The study drew attention to the overriding importance of ethical review of research in low and middle income countries[3]. At the time of the TROVAN study, there was no formal regulatory system of ethics review, nor a set of National biomedical research guidelines.

This has been corrected to a considerable extent with the establishment of the National Health Research Ethics Committee (NHREC) and the National Code of Health Research Ethics (NCHRE).

The NCHRE and the National Health Bill have to a considerable extent breached the gap that existed in the pre-2006 era. Be that as it may, the Bill is yet to receive Presidential assent. The effect of this is that its provisions cannot be enforced by or against any one. There is therefore a need for a legally enforceable legislative instrument in order to remove any questions about legal accountability.

The absence of a National Health Act[4] to back up the National Health Policy has been described as a fundamental weakness which should be corrected quickly[5]. This weakness means that there is no health legislation describing the national health system and defining the role and responsibilities of the three tiers of government and other stakeholders in the system. This has led to confusion, duplication of functions and sometimes lapses in the performance of essential public health functions.

As shown by this project, contract law and tort law have direct reflection on certain aspects of research ethics governance. These areas of law have mainly been developed by judge made laws or common law. Codifying these laws will definitely go a long way in contributing to

[3] Remigius N Nwabueze., (2006) "Litigating the TROVAN Tragedy"., in "Review of a Comparative International Workshop Held at Faculty of Law, University of Toronto, on 16-18 June, 2005., Brown Book Co. Ltd, Toronto.
[4] The Bill becomes an Act once it has received Presidential Accent.
[5] Nigeria Health Watch, 2nd June, 2008. Retrieved from www.nigeriahealthwatch.com on 8th April, 2011.

development of research ethics governance. Similarly, there are various legislations, codes, regulations and directives, some which are not legally enforceable. Consequently, the need for a legally enforceable legislative instrument cannot be over emphasized. The existing law could be reviewed and put together in a single legislation as this will be a “one stop” resource material for researchers.

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