STATUTORY SAFEGUARDS FOR HEALTH RESEARCH PARTICIPANTS IN NIGERIA: A COMPARATIVE ANALYSIS

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Abstract

For a long time in history, the tales of health research involving humans have been like that of vile assailants and their pitiable victims. These victims (participants) were not only misinformed but were also exposed to unethical practices highly inimical to their physical, psychological, social and emotional well-being. While experiments like the Tuskegee syphilis study and the Nigerian Trovan study recorded a good number of deaths, experiments like the Stanford Experiment, Albert Kigman and Herbert Copelan Experiment caused severe impairments on the credulous participants. To ensure that these unethical practices were only found in history archives, international and domestic communities established certain legal frameworks, international standards and best practices to ensure that human participants were properly protected. These frameworks equally made provisions for regulatory institutions to ensure that these established frameworks are complied with. However, the pertinent question remains, has the creation of these legal frameworks totally eradicated unethical conducts in health research involving human participants in developing countries? Has Nigeria's

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approach on the subject matter been effective? Or has it been a case of docile institutions and failure to comply with the available legal frameworks? To provide plausible answers to these disconcerting questions, the paper will undertake a comparative analysis of some selected legal frameworks in Nigeria and in USA and the said comparison will revolve around the process of obtaining informed consent from the research participants, vulnerable population, selection/ recruitment process of research participants and the ethical review process as it relates to the protection of these human research participants. While at it, the paper found that despite minute disparities, there were huge similarities between the two jurisdictions (Nigeria and USA). Consequent upon these findings, the study also made some recommendations. This paper, while adopting the doctrinal methodology of research, employed the analytical and comparative research approaches.

Keywords: Ethical Review, Informed Consent, Vulnerability, Compensation, Human Participants.

1. Introduction

The role of health research has increased as a result of advancements in global health, digital technologies, and ongoing issues with health systems, as well as international commitments like achieving universal health coverage. These advances in health research have resulted in the creation of diagnostic instruments and technology that facilitate prompt and precise disease diagnosis. New treatments for a variety of illnesses, including cancer, allergies, HIV/AIDS, pulmonary disease, and others, have also been developed as a result of it. However, concerns about the ethics of research involving

human participants have a long history. In the past half-century, the level of oversight on research involving human subject has exploded from almost none to what is now an exhaustive system of protections.[1] The focus on health research governance or the regulation of research involving human subjects was catalyzed in Nigeria by the controversial and unethical clinical trial of Pfizer's experimental treatment for epidemic meningitis, better known as *trovan*. Out of the two hundred Nigerian children who participated in the trial, eleven of them died— five on the experimental arm and six on the control arm of the trial. Following the trovan clinical trial, which precipitated into litigation both in Nigeria and the United States of America,[2] there were increased calls for greater scrutiny of research involving human participants in Nigeria. In response to such calls, the federal government of Nigeria took steps to establish a comprehensive system of research ethics review in Nigeria, as well as other regulatory structures and infrastructures for research governance in the country. Although there was an attempt to establish a formal ethical regulatory framework and infrastructure for research in Nigeria in 1980, the system established was largely moribund until it was reconstituted by the federal government of Nigeria around 2006 through the establishment of the National Health Research Ethics Committee (NHREC). Subsequently, the National Code of Health Research Ethics

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1 B Salhia and V Olaiya "Historical Perspectives on Ethical and Regulatory Aspects of Human Participants Research: Implications for Oncology Clinical Trials in Africa" [2020] JCO Global Oncology 959.

2 *Abdullahi v Pfizer Inc*., 562 F3d 163 (2d Cir 2009)

and the National Health Act of 2014 were also created.[3] Despite the establishment of these legal frameworks, it appears that unethical health research continues to thrive in Nigeria. Thus, this foregoing state of affairs raises an important question which will form the crux of this paper—are these frameworks for the regulation of health research in Nigeria inadequate or is the major challenge failure to comply with the laid down rules and regulations? It is against this backdrop that this paper will make a bold attempt to identify the reason(s) for the increase in unethical research despite the presence of these regulatory frameworks. To achieve this, under the succeeding paragraphs, a comparison of selected legal frameworks from two jurisdictions (Nigeria & USA)[4] on the protection of human research participants will be conducted particularly in the following areas:

i) Recruitment of human research participants
ii) Informed consent,
iii) Vulnerable groups/population
iv) Ethical review process

It is also pertinent to point out that the comparative analysis will be carried out with specific reference to four key legislations operative in both jurisdictions.

i) Code of Federal Regulations (CFR) **(United States)**

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[3] J,Nabyonga-OremJAAsmani and M, Makanga "The State of Health Research Governance in Africa: What Do We Know and How Can We Improve?" (2021) 19 Health Research Policy and Systems).

[4] 'What is Comparative Analysis and how is it Used?' (*Indeed Career Guide,* 25 June 2022) <https://www.indeed.com/career-advice/career-development/comparative-analysis> accessed 27January 2024.

ii) Belmont Report **(United States)**
iii) National Code of Health Research Ethics **(Nigeria)**
iv) National Health Act, 2014 **(Nigeria)**

2. Recruitment of Human Research Participants

Recruitment is generally the first contact between researchers or investigators and prospective participants; it is a prelude to informed consent.[5] It can be best described as a dialogue between an investigator or researcher and a prospective participant before intimation of the consent process.[6] It involves identifying potential research participants and providing them with the information to establish their interest in joining a proposed research study.[7] Under Nigerian laws,[8] research is deemed to be ethical if such a research process allows for a fair recruitment of participants based on the scientific objective of the research. Hence, strategies employed by the researcher or investigator in the recruitment of participants must reflect ethical standards. It should exclude those who are excessively susceptible to harm.[9] It

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5 'Recruitment Settings and Procedures' (*Research Integrity* 23rd September 2020) <https://www.unr.edu/research-integrity/human-research/human-research-protection-policy-manual/300-recruitment-settings-and-procedures> accessed 27 January 2024.

6 N Mahonar and others, "Recruitment of Research Participants," Handbook of Research Methods in Health Social Sciences (Springer Singapore 2019) <http://dx.doi.org/10.1007/978-981-10-5251-4_75> accessed April 14, 2024

7 *Ibid*.

8 Under this heading, "under Nigerian laws" signifies relevant Nigerian laws on the protection of human research participants.

9 Quaere: who are those susceptible to harm?

should not also, without explicit reason, exclude children, pregnant women, disadvantaged groups, groups with constrained autonomy, and other vulnerable populations, especially research that can enhance their health and well-being. However, specific safeguards should be made available by the researcher or investigator to protect them.[10] Just like in Nigeria, the recruitment of participants is one of the conditions to be satisfied before getting research approval from the ethics committee under US laws.[11] While Nigeria uses the term "fair," the US settles for "equitable." However, the disparity is of no importance as it is purely one of semantics. In determining the equitable nature of any recruitment process, the Institutional Review board (IRB)[12] is obliged to take into account the purpose of the research and the setting in which the research is conducted. The IRB is also obliged to consider the special problems peculiar to vulnerable groups.[13] In summary, both jurisdictions agree that the recruitment of human participants must be as fair as the research process itself.

3. Informed Consent

Having crossed the recruitment stage, the next step is to obtain consent from the recruited participants. Contextually, informed consent is a process whereby individuals are informed of the risks and benefits of a study and allowed to

[10] See section F(c), NCHRE.

[11] Under this heading, "under the US laws" signifies relevant US laws on the protection of human research participants.

[12] IRB is a body responsible for the ethical review process.

[13] 45 CFR 46.111.

agree or not agree to participate. The question of informed consent came up in the 1990s in the United States of America during the Jesse Gelsinger saga. Jesse Gelsinger, an 18-year-old American, wanted to help others overcome the same metabolic disorder he had. So, he agreed to enter a gene therapy trial. A short time later, he became the first person to die because he participated in gene therapy research. His death would be but one of several unintended consequences which resulted in a lawsuit and investigation by the government. It also resulted in the delay of some other clinical trials, and the creation of a new regulatory process for gene therapy trials in the US.[14]Whether there was informed consent was the main unanswered question surrounding his death. Gelsinger was not informed, according to a family attorney, that three monkeys had died from severe liver inflammation and a clotting condition following injections, nor that numerous other patients had encountered terrible side effects from the therapy. As a result, the US Food and Drug Administration (FDA) suspended the Pennsylvania trial, citing a failure to train staff adequately, develop basic operating procedures and obtain informed consent.[15]Under Nigerian laws,[16] informed consent is a *sine qua non* for the ethical conduct of research, and a must-satisfied condition for a research to be approved by the appropriate Health Research

[14] B Sibbald, 'Death But One Unintended Consequence of Gene-Therapy Trial' Canadian Medical Association Journal (2001) 164(11) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC81135/> accessed 27 January 2024.

[15] *Ibid*.

[16] National Code of Health Research Ethics & National Health Act,2014.

Ethics Committee (HREC).[17] For consent to be valid, adequate information must be provided at the educational level not higher than that of individuals with at most nine years of education.[18] That is to say, the information must be provided in a manner which can, at most, be easily comprehended by a secondary school student. Consequently, such information must be free of unnecessary verbiage, legalism, jargon, and truth-dumping. The design of the research must also be appropriate for the type of research, expected participants, risk anticipated and the research context.[19] To ensure recall of pertinent information, consent forms shall not exceed eight pages.[20]Consent is a requirement under US law, which is the same as that of Nigeria, in order for research to be conducted ethically. However, there are some procedural variations. First, under US law, informed consent may only be obtained in situations when the potential participant or his legally recognized agent has had enough time to debate and deliberate whether or not to engage.[21]While this provision is lacking in Nigerian laws, it resonates with the provision of the Belmont Report on diminished autonomy. It helps to ensure that prospective participants are not under undue influence or indirectly coerced to consent to such research or experiment. Second, the United States of America laws make it mandatory that the investigator or researcher must not only present the

17 HREC stands for Health Research Ethics Committee.

18 Section F(f)(1), NCHRE.

19 Section F(f)(2, NCHRE.

20 Section F(f)(3), NCHRE.

21 45 Code of Federal Regulations (CFR) 46.116(2).

information adequately and concisely but also in the language the participant can easily understand.[22] This ensures that the participant or his legally recognized representative is not misinformed about any area of the research. Third, the United States of America laws exclude the inclusion of exculpatory words through which the participant is made to waive his rights or release the investigator or researcher from liability.[23] Furthermore, the laws of both jurisdictions agree that the adequate information which the investigator or researcher is obliged to provide shall center on the title of the research, the purpose of the research, the procedure of the research, the expected duration of research and the participant's involvement, risks involved, the participant's cost and benefit. It will also center on confidentiality, voluntariness, the procedure for termination of the research, consequences of participants decision to withdraw, detailed contact information of researcher and other important people involved etc.[24] Also, to circumvent inconsistencies that may occur as a result of failure to keep records of the informed consent documents, the laws of both jurisdictions further provide that the consent process[25] must be kept for record purposes.[26] However, only the US laws go further to stipulate the processes involved in such documentation. As reported by

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22 45 CFR 46.116(3).

23 45 CFR 46.116(6).

24 See section F(f)(5) and 45 CFR 46. 116(b)&(c).

25 Consent process in this context includes: provision of adequate information and the participant's acceptance etc.

26 Section F(f)(12), NCHRE.

the US law,[27] firstly, the process shall be documented by the use of a written informed consent form approved by the appropriate IRB and signed by the participant or his legally recognized representative.[28] Secondly, the informed consent form must be posted on the federal website after the trials are closed to recruitment and not later than sixty days after the last study visit by the participant.[29]From the foregoing, it can be concluded that the consent process in any human health research has three components: information, comprehension, and voluntariness. According to, the Belmont Report on the component of comprehension, the manner and context in which information is conveyed is as important as the information itself. The level of comprehension is also important within the context of the individual's ability to understand the information, with an emphasis that the obligation for ensuring subject understanding increases in importance relative to the level of risk posed by participation in the study. The National Commission[30] suggests that some level of questioning the subject to ensure comprehension is appropriate and even suggests that written responses to questions may be appropriate if risks are exceptionally high.

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[27] Code of Federal Regulation.

[28] 45 CFR 46.117(a).

[29] 45 CFR 46.116(h)(3).

[30] The Belmont Report was written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission, created as a result of the National Research Act of 1974, was charged with identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and developing guidelines to assure that such research is conducted in accordance with those principles.

If the participation of participants with compromised abilities is anticipated, researchers or investigators must be particularly diligent in evaluating the level of comprehension by the participant's representative and ensure that the representative is indeed capable of representing the best interests of the subject. The report even suggests that the representative might need to be present or available during the research interventions to withdraw the subject from the study if the representative perceives that withdrawal may be in the subject's best interest.[31] The US Food and Drug Administration[32] ("FDA") believes that obtaining a research participant's verbal or written informed consent is only part of the process. Informed consent, as indicated earlier, involves providing a potential participant with adequate information to allow for an informed decision about participation in the clinical investigation; facilitating the potential participant's understanding of the information; an appropriate amount of time to ask questions and to discuss with family and friends the research protocol and whether he should participate; obtaining the potential participant's voluntary agreement to participate; continuing to provide information as the clinical

[31] M.G White, "Why Human Subjects Research Protection Is Important" (2020) 20 Ochsner Journal 16.

[32] The United States Food and Drug Administration (FDA or US FDA) is a federal agency of the Department of Health and Human Services. The FDA is responsible for protecting and promoting public health through the control and supervision of food safety, tobacco products, caffeine products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), cosmetics, animal foods & feed and veterinary products.

investigation progresses or as the subject or situation requires; and the provision of sufficient opportunity for the participant to consider whether to participate.[33] FDA considers this to include allowing sufficient time for participants to consider the information and providing time and opportunity for the participant to ask questions and have those questions answered. The investigator (or other study staff who are conducting the informed consent interview) and the participant should exchange information and discuss the contents of the informed consent document. This process must occur under circumstances that minimize the possibility of coercion or undue influence.

4. Vulnerable Groups/Population

Vulnerable groups can be explained as a population within a country that has specific characteristics that make it at a higher risk of needing humanitarian assistance than others or being excluded from financial and social services.[34] In research involving humans, additional protective covers are usually made available for vulnerable groups who are easily disadvantaged. Under Nigerian laws,[35] albeit references made to pregnant women and disadvantaged groups in general, specific provisions are only made for people with cognitive

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[33] See 21 CFR 50.20.

[34] CHA. Kuran and others, "Vulnerability and Vulnerable Groups from an Intersectionality Perspective" (2020) 50 International Journal of Disaster Risk Reduction 101826<https://www.sciencedirect.com/science/article/pii/S2212420920313285> accessed 28 January 2024.

[35] National Code of Health Research Ethics & National Health Act,2014.

impairments and children. The US laws,[36] on the other hand, extend these provisions to include pregnant women, neonates, prisoners and fetuses, making it more encompassing than the Nigerian laws. Under the US Laws, participation of pregnant women and fetuses, is heavily subject to scientifically appropriate pre-clinical studies which involve studies on pregnant animals and non-pregnant women. The data obtained from such a pre-clinical study must contain the research's potential risk on pregnant women and fetuses. Also, no inducement (monetary or otherwise) shall be offered to terminate a pregnancy for the sake of research.[37] The level of protection offered to neonates (newborns), on the other hand, is dependent upon the condition of the neonate. In the case of neonates with uncertain viability, the IRB must ensure that the research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability and any risk involved is the least possible for achieving this objective.[38] It shall equally ensure that the purpose of the research is for the development of important biomedical knowledge which cannot be obtained by other means and does not involve any added risk to the neonate in such pursuit.[39] In the case of a non-viable neonate, the IRB must ensure that the vital functions of the neonate will not be artificially maintained, the heartbeat or respiration of the neonate will not be terminated, the risks involved are

[36] Code of Federal Regulation and Belmont Report.

[37] 45 CFR 46.204(h).

[38] 45 CFR 46.205(b)(1)(i).

[39] 45 CFR 46.205(b)(1)(ii).

minimal, and the purpose of the research is for the development of important biomedical knowledge that cannot be obtained by any other means.[40] The provisions applicable to children are extended to such cases involving viable neonates.[41] Above all, consent must be obtained from the legally recognized representatives of these neonates. For prisoners to be recruited as participants, the proposed research shall involve the study of the possible causes, effects, and processes of incarceration; the study of prisons as institutional structures or of prisoners as incarcerated people; the study of conditions particularly affecting prisoners as a class; and the study of practices which have the probability of improving the health or wellbeing of the prisoners.[42] Above all, the research must present no more than minimal risk and inconvenience to the prisoners (participants). Furthermore, provisions are made for children under the laws of both jurisdictions. Under Nigerian laws,[43] children are described as legal personalities younger than the age of 18. For this category of legal persons to be eligible for recruitment, consent must be obtained. In the case of children younger than twelve, the consent of both parents or one of the parent or legal guardian who has the primary responsibility of the child as at the time of the proposed research. Children between the ages of twelve and eighteen will, in addition to their parents' consent, be required to give their consent. The

40 45 CFR 46.205(c).

41 45 CFR 46.205 (d).

42 45 CFR 46.306.

43 National Code of Health Research Ethics & National Health Act,2014.

Nigerian laws equally make provisions for emancipated minors. These set of minors are allowed to give consent in their cognizance. Under US laws, the scope of coverage is not limited to just obtaining consent as a prelude to the eligibility of children. These laws, in addition to consent, require that such research must not involve greater than minimal risk.[44] In research involving greater than minimal risk but representing the prospect of direct benefit to the children, the risk involved must be justified by the anticipated benefit to the children and the relation of the anticipated benefit to the risk must be at least as favourable to the children as that presented by available alternative approaches.[45]If the proposed research involves greater than minimal risk and no prospect of direct benefit to the children but is likely to yield generaliseable knowledge about the participant's disorder or condition, then, for the research to be approved, the risk shall represent a minor increase over minimal risk. The invention or procedure must present experience to the children that are reasonably commensurate with those inherent in their actual or expected conditions.[46] Children who are wards of the State or any other institution or entity are entitled to participate in health research. However, such research must be related to their status as wards of the State and shall be conducted in schools, camps, hospitals, or institutions with similar settings in which majority of the children involved are not wards.[47] In addition

[44] 45 CFR 46.404.

[45] 45 CFR 46.405.

[46] 45 CFR 46.406.

[47] 45 CFR 46.409(a)(1)-(2).

to the ward's guardian or *loco parentis*, there must be an appointment of an advocate for him. The advocate shall be an individual who has the background and experience to act in, and agreed to act in, the best interest of the child for the duration of the child's participation in the research and who is not associated in any way with the research or the investigators or guardian organization.[48] From the wordings of the Nigerian laws one can say that cognitive impairment occurs when an individual is unable to think, remember, or reason. Regardless of this, they shall not be excluded from serving as participants. However, the HREC and researchers are mandated to ensure that the process is fair to them and does not pose any threat.

5. Ethical Review Process

Under Nigerian laws, the NHREC and HREC are in charge of reviewing and approving research involving humans to be conducted in Nigeria. Thus, for any institution or researcher to be qualified to conduct health research, such institution must have a registered health research ethics committee, registered with the National Health Research Ethics Committee.[49] Each HREC shall have at least five members. In the case of more than five members, the number of members shall be odd to ensure that a tiebreaker is possible in the case of a tie. The registered and properly constituted HREC shall possess the necessary competence and expertise required to review specific research activities and ascertain the

[48] 45 CFR 46.409(b).

[49] See section C for the registration requirements.

acceptability of the research in terms of institutional regulations, applicable laws, and standards of professional conduct. It must include at least one member whose primary concerns are in scientific and non-scientific areas respectively. The HREC shall also be comprised of one member who shall not be affiliated with the institution or part of the immediate family of a person affiliated with the institution. In the event of a review involving vulnerable participants, the HREC is expected to co-opt one or more individuals knowledgeable and experienced in working with these participants.[50] Furthermore, at the risk of repetition but for emphasis sake, the HREC is in charge of approving, disapproving, terminating, suspending, or modifying the terms of any research involving human participants. The research application should be deliberated upon at regularly convened ordinary meetings of the HREC at which a majority of the members are present, including a member whose primary concerns are in non-scientific areas. Approval or disapproval shall be by discussion and consensus or a simple majority of members present at the meeting. It may, during the meeting, invite representatives from the applicant (institution) or other people who it may consider relevant to provide information pertinent to the research.[51] Notably, the HREC must have a maximum of three months to conclude all deliberations and reach a resolution. If it deems an application to be complex, it is expected to refer such application to the NHREC and the applicant duly informed within the stipulated

[50] See section D, NCHRE

[51] Section E(d) NCHRE

three months. If it fails to conclude within three months and also does not refer the case to the NHREC, the applicant shall have the right to appeal to the NHREC. In such a situation, the NHREC reserves the right to reallocate the review process to another HREC and impose sanctions on the defaulting HREC. The HREC shall, after deliberation, notify the applicant in writing of its decision. If it decides to disapprove the application, it should attach its reasons for disapproval in its written notification and also allow the applicant to respond in person or in writing within three months of receipt of such notification. Moreover, the HREC is statutorily empowered to expedite the review of some research applications. This occurs where the proposed research involves no more than minimal risk, where it does not involve the vulnerable population, does not contain serious methodological or ethical flaws, but involves minor changes in previously approved research.[52] This form of review may be carried out by the HREC's chairperson or designee from among members of the HREC. The reviewer (HREC's chairperson or designee) shall exercise all the powers of the HREC except the power to disapprove the research. After approval, the chairman of the HREC shall bring such expeditiously reviewed research to the next HREC meeting for discussion and possible ratification.[53] In addition, the HREC must after approval of a research application, conduct continuing oversight of the research. It shall have the authority to observe or cause to be observed on its behalf the research and consent process to ensure

[52] Section E(f), NCHRE

[53] See section E, NCHRE.

compliance with the highest scientific and ethical standards. In multi-institutional research, the principal investigator at each research site may apply to the institutional HREC for review. An HREC may adopt the approval given by another HREC rather than conducting a fresh review. Where there are discordant comments on the application, the applicant should submit the different comments from the different HRECs to their institutional HREC for consideration and possible reconciliation.[54] In international collaborative research, only the principal investigator who is affiliated with a registered institution in Nigeria can apply for review of research. The NHREC, other than the HREC, may review applications where research is nationwide in coverage, involves more than three research sites in Nigeria, research was referred to it by an HREC, there is no HREC in an institution and the institution does not have an HREC corporative agreement etc.[55] Conversely, under US laws, the IRB, an equivalent of HREC, is charged with the responsibility of reviewing research applications. They provide core protection for human research participants through advance and periodic independent review of the ethical acceptability of proposals for human research. They were codified in US regulation just over three decades ago and are widely required by law or regulation in jurisdictions globally. Its composition is similar to that of HREC. Thus, any IRB should, among others, have at least five members who possess the relevant competence and expertise. However, unlike HRECs, IRBs are mandated

[54] Section E(m), NCHRE

[55] Section E(q), NCHRE

to prepare and maintain a current list of the IRB members identified by names, earned degrees, representative capacity, indicated experience, and each member's chief anticipated contributions to the IRB. Just like an HREC, an IRB undertakes its work either in a convened meeting or by using an expedited review procedure.[56] However, in the case of an expedited review process, it reserves the right to adopt a method for keeping all members advised of research applications that have been approved by the procedure, other than the Chairman introducing at the meeting in an HREC. IRB does not have a stipulated time to carry out its task, unlike an HREC which has three months to round off its review process. Moreover, since the inception of IRBs, the research landscape has grown and evolved, as has the system of IRB review and oversight. Independent review of clinical research by an IRB is required for US studies funded by the Department of Health and Human Services (DHHS) and other US federal agencies, as well as for research testing interventions—such as drugs, biologics, and devices—that are under the jurisdiction of the US Food and Drug Administration (FDA). US research institutions can and often do extend federal regulatory requirements to all of their human research. Research conducted outside of the United States but funded by the US government is subject to the same US federal regulations and so requires IRB review or equivalent protections.[57] Research conducted outside of the United States, not under an investigational new drug that

[56] 45 CFR 46.106 & 46.110.

[57] *Op Cit*.

submits data to the FDA for a new drug or biologic license application, must comply with Good Clinical Practice guidelines, which include review and approval by an independent review committee and informed consent.[58] In addition, under US laws, research approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials shall not approve the research if it has not been approved by the IRB.[59]This is to ensure that research applications are properly scrutinized. It would have been more effective if the US laws had gone ahead to stipulate situations where this provision shall be applied. Alternatively, employ the word "shall" to cover all possible cases.

6. Findings

As political entities, Nigeria and the United States of America have had their share of ethical violations in research involving humans. Against the backdrop of these ethical violations, certain international and domestic institutional and legal frameworks have been put in place by both jurisdictions. These frameworks were outlined, discussed, and compared in the preceding paragraphs. This comparison of specific areas like recruitment of research participants, informed consent, vulnerable groups, and ethical review process laid bare some pertinent issues which this paper in this paragraph will itemize as its findings.

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[58] C, Grady 'Institutional Review Boards' (2015) 148 Chest 1148.

[59] 45 CFR 46.112.

i. Both jurisdictions made provisions for the recruitment of research participants. To them, the process of recruitment of research participants must be fair enough to ensure that participants are not disadvantaged. In achieving this, the researcher must attempt to recruit potential participants who are appropriate to answer the research question(s). For instance, if the research question is centered on the behavioural effects of incarcerated individuals, then incarcerated individuals should be recruited for the study. The same applies to studies which seek to determine the efficacy of drugs to be used by a category of individuals. This helps to ensure a fair distribution of the burden and benefits of research and it is in tandem with the principle of justice.

ii. Under both jurisdictions, the recruitment process must also justify the involvement of participants who are susceptible to harm. This was interpreted to not mean that they should be deliberately excluded from research but merely to accompany their recruitment with a statement addressing the reason for their involvement.

iii. Both US and Nigeria refer to these individuals as vulnerable groups. However, the NHREC Code creates a confusion by introducing another class that must be excluded- individuals who are excessively susceptible to harm.[60] This begs the question, since

[60] See Section F NHREC Code.

they have all been grouped into a general class referred to as the vulnerable groups, what is the justification and rational for creating a new class-individuals excessively susceptible to harm. Furthermore, who are those excessively susceptible to harm?

iv. Both jurisdictions agree that informed consent is an ethics-friendly device which usually comes into play after the recruitment process has been concluded. It helps to establish a participant's prior knowledge of the risks and benefits involved in research, whether biomedical or behavioural. Both laws impose this obligation on the investigator, institution or researcher (as the case may be). The US laws, before detailing the steps a researcher or investigator is required to follow in satisfying this obligation, warn that informed consent can only be obtained in circumstances where the researcher and the prospective participant have equal bargaining power. If the circumstance is such that the prospective participant cannot discuss and consider the terms of his participation, then his name should be struck out from the list of prospective participants, no matter how advantageous or helpful he would have been. The US laws also prohibit the use of unfathomable lingos. Stated differently, the language used to explain information about the research must be that

which can be easily understood by the participant. In lieu of this, the Nigerian laws provide that the necessary information needed to make an informed decision must be prepared in a way that can be easily understood, at most, by a junior secondary student (education level not higher than that of individuals with at most nine years of education). The question is what is the clear basis for assessing what can be understood by a junior secondary school student, given the disparity in intelligence quotient? To provide some form of clarity on this, they maintain that the written statement should not exceed eight pages and should not be fraught with unnecessary legalisms, verbiage, jargon etc. Moreover, both laws emphasize the importance of documenting safe keeping of the informed consent document for record purposes. However, only the US laws specify how this record keeping can be carried out. This ensures that the IRB does not develop its forms and procedures to satisfy this rule. Above all, it ensures that uniformity is achieved in the record keeping process.

v. Strange to Nigerian laws but known to US laws is the provision for broad consent. Broad consent is a category of consent which was included in 2019 by the Office of Human Research Protections. As maintained in 45 CFR 46.116, broad consent can only serve as an alternative to informed consent where the issue pertains to the storage, maintenance,

and secondary research use of identifiable private information or identifiable bio specimens. Broad consent requires most of the elements of informed consent along with (but not restricted to) statements as to whether the participant will share in the profit of the research, statements as to the private information or bio specimen that might be used in the research and the duration of its usage.

vi. Both jurisdictions did not just outline the vulnerable groups to include pregnant women, children, prisoners, disadvantaged individuals, and groups with constrained autonomy but also made provisions to safeguard them from abuse and harm. However, the US laws can be adjudged to be more inclusive and more protective than the Nigerian laws. For instance, under the NHREC Code special provisions are only made for children and individuals with cognitive impairments. Consequently, the only form of protection a pregnant woman has is the right not to be excluded from being recruited; and in the case of involvement, explicit reasons for such involvement. Ditto for prisoners. Au contraire, US laws make robust provisions for these persons identified as vulnerable groups. On the part of children which the Nigerian laws equally made provisions for, the US laws go beyond the obtainment of consent to insisting that the research must be for the benefit of the children and with minimal risk.

vii. Both jurisdictions place the responsibility of protecting the rights and welfare of people who participate in research on their respective ethics committees— HREC and IRB. Any proposed research must be reviewed and approved by these committees before it is conducted. This review process is categorically grouped into two: full review process and expedited review process. While the full review process entails deliberations at regularly conducted ordinary meetings, the expedited review process involves approval from the committee's chairperson or designee. As agreed by both jurisdictions, an expedited review process occurs only when the risk involved is minimal and does not include the vulnerable groups. Thus, research involving pregnant women, children, prisoners etc. cannot be reviewed expeditiously; it must go through the full review process.

viii. Peculiar to Nigerian laws is the idea that the review process shall span no fewer than three months. This ensures that the trend in the Nigerian litigation system is not extended to the protection of human research participants. Under US laws, an institution may, in addition to an IRB's approval, review the approved research application. This is to ensure that all the ethical boxes are checked. Under Nigerian laws, on the other hand, the curtain is drawn after the HREC or NHREC's review.

7. Conclusion and Recommendations

The work x-rayed the relevant legal frameworks for the protection of research participants in Nigeria and USA and outlined the differences and similarities in these laws. It was found amongst other things that both jurisdictions share a lot in common. Thus, despite minute disparities, both jurisdictions offer comprehensive protection to research participants via the provisions of their respective legal frameworks. It was also found that unlike its counterpart (USA) the Nigerian legal frameworks do not offer adequate protection to the vulnerable population. This flows from the fact that some provisions of its laws are fraught with ambiguities and are not comprehensive enough to cover all possible cases. To remedy these supposed ambiguities, the following recommendations were made.

i. Amend the Relevant Legal Frameworks

The relevant legal frameworks in Nigeria especially the NHREC Code should be reviewed and amended to cure certain ambiguities and equally extend its protective cover to non-referenced situations.[61] For instance, the issue concerning individuals with excessive susceptibility can be addressed by mentioning these individuals or outlining instances where excessive susceptibility can be inferred. Also, given the vulnerable state of pregnant women, neonates, and prisoners, additional provisions should be made to ensure that they are

[61] Especially section 12 of the Constitution of the Federal Republic of Nigeria 1999.

protected. Inspiration may be drawn from the provisions of US laws during this amendment.

ii. Adjust the Requirements for Research Approval

The Nuremberg Code emphasizes the need to ensure that a proposed research or experiment is first carried out on animals before being carried out on humans. This will enable the researcher or investigator to have an understanding of the likely effects such research will have on humans. Given that this international standard is not reflected in our domestic laws, this paper recommends that it be included as one of the requirements for biomedical research approval.

iii. Adopt a Two-Way Research Review Method

The review process, as explained in the preceding paragraphs, entails approval or disapproval by the appropriate HREC after assessing the consent documents and other important documents. While this process ensures that ethical standards are maintained, the likelihood that corruption may disrupt the idea behind it is high, hence, a two-way research review is recommended. That way, the NHREC will further approve the research after an HREC's approval.