PROTECTION OF THE RIGHTS OF NIGERIAN RESEARCHERS AND PARTICIPANTS OF INTERNATIONAL HEALTH RESEARCH

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Abstract

The benefits of health research to populations have proven that the global community cannot dispense with such practices. There has been an increase in the number of international collaborative research involving human participants in Nigeria and it is necessary to protect the rights of Nigerian researchers and participants of research. The rights of both parties must be protected because they could be subjected to harm and unethical activities if the research field is not carefully regulated. This article discusses the regulatory framework that protects researchers and participants of health research in Nigeria. It discusses Biobanking and genomic research and some ethical issues associated with such research that could violate the rights of both researchers and participants. It analyses the issues that need to be sorted out to ensure that these frameworks are effective. The article recommends that health institutions should establish research ethics committees in accordance with regulatory directions and equip them to adequately perform their responsibilities.

Keywords: International research, Collaborative health research, Rights, Participants of research, Nigerian researchers, Biobanking

1. Introduction

Research is an important aspect of the medical field and medical practitioners often find it necessary to conduct research during their careers and practice.[1] Research is mostly carried out to 'advance the frontiers of knowledge; to undertake trials to prove and establish developing trends in the fields of medicine; to proffer newer and advanced treatment options; and to discover proven and easier options and procedures'.[2] Clinicians who are also academics are motivated to conduct research and publish the results for the purpose of advancing their careers and receiving elevations at the institutions where they work.[3] In some circumstances, research is carried out for economic gains for example, pharmaceutical companies who are required to perform clinical trials on drugs and other products before they are made available to the public.[4] The 1996 Pfizer trial portrays the importance of research regulation in the medical field, as a pharmaceutical company caused the death and disability of several children in Kano state, Nigeria, after carrying out illegal trials on children with meningitis with an unregistered drug.[5] The Pfizer incident has led to concerns as regards the motivation of research sponsors, who conduct research in low- and middle-income

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[1] Oscar Gonzalez-Perez and Cesar Ramos-Remus, 'The Importance of Physician Engagement in Medical Research' (2025) 12 Frontiers in Medicine 1537023.

[2] Olaitan O. Olusegun and Oluwadamilola O. Adejumo, Legal Prescriptions for Medical Practitioners: A Handbook of Medico-Legal Issues and Rights Protection in Nigeria (Krafts Publishers, Nigeria 2023) 125

[3] Patrick I. Okonta, 'Ethics of Clinical Trials in Nigeria' (2014) 55(3) Nigerian Medical Journal 188-194.

[4] Schott G et al., 'The Financing of Drug Trials by Pharmaceutical Companies and Its Consequences: Part 2: A Qualitative, Systematic Review of the Literature on Possible Influences on Authorship, Access to Trial Data, and Trial Registration and Publication' (2010) 107(17) Dtsch Arztebl Int 295-301.

[5] Belinda Archibong and Francis Annan, 'What do Pfizer's 1996 Drug Trials in Nigeria Teach us about Vaccine Hesitancy?' https://www.brookings.edu/articles/what-do-pfizers-1996-drug-trials-in-nigeria-teach-us-about-vaccine-hesitancy/ accessed 23 January 2026.

countries (LMICs) like Nigeria and the safety of research participants who might be harmed if regulatory measures are not established.[6]

The need to break new boundaries in the field of healthcare and find solutions to diseases in LMICs has over the past years, led to a significant number of international collaborative health research between persons in LMICs and other countries, particularly high income countries.[7] Research governance is pertinent in international collaborations due to the risk of exploitation of researchers especially from countries with superior powers and resources.[8] A possible consequence of non-regulation is parachute research, a situation where researchers from developed countries conduct research in LMICs without supervision and control from resident researchers.[9] In parachute research, the contributions of resident researchers are hardly recognised and their roles are sometimes only limited to the collection of samples and data. Upon completion, samples and data collected are taken away to the developed countries for further research.[10] This situation happened, for example, during the Ebola pandemic and it was reported that international researchers took away specimens from West African countries to their own countries without compliance with extant regulations in those countries.[11]

Apart from researchers, there are also concerns that the rights of participants may be violated due to their vulnerability that arise as a result of their lower socio-economic levels or their health status.[12] Research activities are thus regulated to ensure that their rights, interests and wellbeing are protected and that they are treated with respect and dignity.[13] Biobanking and genomic research increase the complexities of research with implications for researchers and participants.[14] Studies have for example reported that participants in sub-Saharan Africa find it difficult to easily understand genomic research terms and the methods of obtaining consent due to high levels of illiteracy.[15] Participants require protection and their rights to life and dignity must be preserved, despite their health status and vulnerability. Ignoring the rights of participants could make them wary of future calls for participation in health research and lead to refusal of cooperation, which would affect research and the benefits it brings to Nigeria and its population. The regulatory system on health thus needs to balance the interests of participants and researchers and protect the welfare of parties while at the same time, ensuring that populations benefit from medical breakthroughs.[16]

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[6] Olusegun and Adejumo (n 2) 126.
[7] Nienaber Annelize, 'The Protection of Participants in Clinical Research in Africa: Does Domestic Human Rights Law Have a Role to Play?' (2008) 8(1) *African Human Rights Law Journal* 138-162.
[8] Iqra Chaudhry et al., 'Strengthening Ethics Committees for Health-Related Research in Sub-Saharan Africa: a scoping review' (2022) 12(11) *BMJ Open* e062847.
[9] Oluchukwu L. Obiora et al., 'Data Sharing Considerations and Practice Among Health Researchers in Africa: A Scoping Review' (2024) 10 Digital Health 20552076241290955.
[10] Aminu Yakubu et al., 'Model Framework for Governance of Genomic Research and Biobanking in Africa–A Content Description' (2018) 1 AAS Open Research 1-18.
[11] Heymann DL et al., 'Partnerships, Not Parachutists, for Zika Research' (2016) 374(16) N Engl J Med 1504–1505.
[12] Bruce G. Gordon, 'Vulnerability in Research: Basic Ethical Concepts and General Approach to Review' (2020) 20(1) *Ochsner Journal* 34-38.
[13] Sheila Varadan, 'Article 5: the Role of Parents in the Proxy Informed Consent Process in Medical Research Involving Children' (2020) 28(3) The International Journal of Children's Rights 521-546.
[14] Chaudhry et al., (n 8).
[15] Mbuagbaw L et al., 'The Challenges and Opportunities of Conducting a Clinical Trial in a Low Resource Setting: The Case of the Cameroon Mobile Phone SMS (Camps) Trial, An Investigator-Initiated Trial' (2011) 12 Trials 1–7.
[16] Olusegun and Adejumo (n 2) 126.

This article discusses the regulation of international or collaborative health research with the aim of highlighting its importance, relevant provisions and the challenges encountered in the attempts at achieving effective regulation. The article is divided into 4 sections, with the first section being the introduction. The second section discusses the international regulatory framework protecting participants of health research in Nigeria with focus placed on the Declaration of Helsinki due to its relevance and recent update. The third section highlights the regulatory framework governing health research generally in Nigeria while the fourth section focuses on the protection of Researchers and Participants of Health Research in International Collaborations. The fifth section analyses biobanking and genomic research while identifying some specific ethical challenges experienced in these innovative procedures. The sixth section which is the concluding remarks, identifies the challenges that could impede the effectiveness of regulations concerning international health research and suggests measures for reforms.

2. International Regulatory Framework on Health Research: The Declaration of Helsinki

The Declaration of Helsinki, a document developed by the World Medical Association (WMA) highlights ethical principles that aim to protect human participants of health research. The WMA recommends that beyond medical practitioners, all persons, groups and organisations involved in human research are expected to comply with the principles of the Helsinki Declaration. It has been amended over the years with the latest edition completed in 2024, making it the most recent international ethical guideline on health research, hence the focus on it in this paper.

The Declaration maintains that progress can only be made in the field of medicine when humans participate in research. The Declaration went on to emphasise the importance of medical research or experimentation by stating that apart from new procedures, treatments and drugs, 'even well-proven interventions should be evaluated continually through research for their safety, effectiveness, efficiency, accessibility, and quality'.[17]An important ethical principle highlighted by the Declaration is that medical research can only be conducted by persons with the appropriate level of education, qualification and knowledge of relevant ethical principles.[18] Also, researchers involved with human trials must never engage in misconduct and must display 'scientific integrity' at all times.[19]

Medical practitioners are allowed to conduct research on the patients they care for, provided such research has 'potential preventive, diagnostic or therapeutic value' and the practitioner strongly believes the research would not be harmful to their health.[20] The Declaration admits that health research sometimes include risks and it is pertinent that researchers assess the expected risks to the participants and ensure that the benefits of the research would outweigh the risks before the commencement of the study.[21] Researchers must take steps to minimise the risks and burdens associated with their research and access, monitor and document such risks.[22] Research with human participants must have commenced with adequate laboratory and animal research.[23] Medical research which is to be conducted on individuals, groups or communities that are particularly vulnerable is only permissible if the knowledge and interventions that would emanate from such research would meet their health needs and benefit them. Researchers should only

[17] Helsinki Declaration, Para 5.
[18] Helsinki Declaration, Para 12.
[19] Helsinki Declaration, Para 12.
[20] Helsinki Declaration, Para 14.
[21] Helsinki Declaration, Para 16, 17.
[22] Helsinki Declaration, Para 17, 18.
[23] Helsinki Declaration, Para 21.

consider those vulnerable persons where it is impossible to use other less vulnerable group or community.[24]

Prior to the commencement of research involving humans, a proposal which must, among other things, outline how the principles of the Helsinki Declaration has been complied with and measures established to compensate participants who are harmed in the process of research,[25] must be submitted to appropriate research ethics committees for their approval.[26] The Declaration also states that research ethics committees are expected to operate in a transparent manner and should be independent enough to resist pressure or manipulation by parties to the research. To perform their responsibilities effectively, committees should be provided with adequate resources and the members of staff must be educated, qualified and trained.[27] Committees have the right to 'monitor, recommend changes to, withdraw approval for, and suspend ongoing research'.[28] The Declaration places a huge importance on the privacy of human participants of health research and the confidentiality of their personal data.[29] Persons cannot participate in research if they have not given their free and informed consent, which is a basic component of respect for the autonomy of humans.[30] It has been stated that 'informed consent remains among the most important ethical requirements in medical research and the *sine qua non* of all research involving human subjects'.[31]

The Declaration urges that complete information concerning all aspects of research should be made available in a language and manner understood by participants. Consent must be documented on paper or electronically and when such documentation is impossible, non-written consent is permissible on the condition that it is witnessed formally and recorded.[32] Persons incapable of giving their consent should not be included in medical research except such research stands to benefit them directly or would pose only a minimal risk to their lives and health.[33] In such cases where they have to participate, their legal representative should be consulted and the predisposition and values indicated by the potential participant should also be considered.[34] A patient's rejection of an offer to participate in research should not affect the doctor-patient relationship or the standard of care the patient should receive.[35] Consent must also be obtained from participants for the 'collection, processing, storage, and foreseeable secondary use of biological material and identifiable or re-identifiable data. When consent could not be obtained for the use of stored data for secondary research, such research can only be conducted upon the approval of a research ethics committee.[36]

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[24] Helsinki Declaration, Para 20.
[25] Helsinki Declaration, Para 22.
[26] Helsinki Declaration, Para 23.
[27] Id.
[28] Id.
[29] Helsinki Declaration, Para 24.
[30] Helsinki Declaration, Para 25; Julie Kent and Ruud ter Meulen, 'Public Trust and Public Bodies: The Regulation of the Use of Human Tissue for Research in the United Kingdom in Christian Lenk', Judit Sandor and Bert Gordijn (eds*) Biobanks and Tissue Research: The Public, the Patient and the Regulation* (Springer, 2011) 18.
[31] *Sine qua non* means an essential condition without which something would not happen; Varadan (n 13) 521-546.
[32] Helsinki Declaration, Para 26.
[33] Id.
[34] Helsinki Declaration, Para 28.
[35] Helsinki Declaration, Para 31.
[36] Id.

3. Regulatory Framework Governing Health Research in Nigeria

Nigerian legal framework has adopted some of the principles outlined in the Declaration of Helsinki and other ethical guidelines. Many laws governing medical research in Nigeria do not include international or cross-border research. An example is the National Health Act (NHA), which was enacted in 2014 to regulate the health system in Nigeria. The Act establishes the National Health Research Ethics Committee to promote health research in Nigeria.[37] The NHA also mandates that participants to any research give their written consent upon receiving complete details concerning the research. When participants are children, the NHA mandates that researchers consider their best interests and obtain informed written consent from their parents or guardians.[38]

Furthermore, the Code of Medical Ethics (CME), a code of conduct that serves as a guide for the practice of the medical and dental professions in Nigeria, regulates biomedical research involving human subjects.[39] The CME also places high importance on the need to obtain the informed consent of research participants and protect their privacy. It specifies that health research should only be conducted in Nigeria when the expected benefits exceed the expected risks. Also, the CME specifies that all teaching hospitals and medical research institutes should establish an Ethical Review Committee, who would consider and approve research protocols before research is carried out. As regards the research concerning new drugs investigations, the CME provides, among other things, that such research must be approved by an ethics review committee, the Federal Ministry of Health, and the National Agency for Food and Drug Administration and Control (NAFDAC). NAFDAC is the agency mandated to among other functions, regulate 'clinical trials for new pharmaceutical products in Nigeria'.[40] The Drug and Related Products (DRP) Act 1993 gives NAFDAC the duty to 'issue a valid clinical trial certificate to companies in respect of their products'.[41] Thus, before clinical trials are undertaken, permits must be obtained from NAFDAC.[42] The principle of informed consent is also stated as a requirement before the commencement of clinical trials. The NAFDAC Guidelines recommends that the most recent version of the Declaration of Helsinki is used as a guideline to achieve ethical clinical trials by all parties involved in research.

4. Protection of Researchers and Participants of Health Research in International Collaborations

International health research is regulated differently in jurisdictions even though some similarities exist in some provisions. In Nigeria, regulatory frameworks protecting researchers and participants of health research in international collaborations include:

4.1 Data Protection Act

The Nigerian Data Protection Act (NDPA) was enacted in 2023 to regulate the processing of personal data and protect the rights and interests of data subjects, including ensuring that they are compensated when their rights have been violated. The NDPA defines 'sensitive personal data' to include information which discloses the health status of an individual.[43] The nature of some health research would require disclosure of health status which makes the NDPA relevant. The NDPA

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[37] NHA, Section 31.
[38] NHA, Section 32.
[39]. See CME, Part B.
[40] Aminu Yakubu and Clement A. Adebamowo, 'Implementing National System of Health Research Ethics Regulations: The Nigerian Experience' (2012) 1(1) BEOnline: Journal of the West African Bioethics Training Program 4.
[41] Olusegun and Adejumo (n 2) 126.
[42] DRP Act, sec 1(2).
[43] Nigeria Data Protection Act, 2023 s 65.

provides that a data controller or data processor shall not process sensitive personal data unless the rights of the data owners have been considered and protected.[44] The NDPA also emphasises the principle of consent with similar provisions to the guidelines stated in the Declaration of Helsinki.[45] Also, all necessary information must be given to data subjects before their personal data is collected.[46] It is important that the data controller and data processor take measures to ensure that personal data collected is secure and maintains integrity and confidentiality.[47] Such protective measures include: 'pseudonymisation or other methods of de-identification of personal data; encryption of personal data; processes to ensure security, integrity, confidentiality, availability and resilience of processing systems and services; processes to restore availability of and access to personal data in a timely manner, in the event of a physical or technical incident…'[48] The NDPA prohibits the transfer of personal data from Nigeria to other countries except the recipient of the personal data is regulated by rules and laws that offer protection to personal data or (b) one of the conditions set out in section 43 of this Act applies. A data controller or data processor shall document the reason why personal data is transferred from Nigeria to another country. Some personal data, due to their nature and the risks associated with them, may require additional specified restrictions on cross-border sharing and it is the duty of the Commission to identify these categories of personal data.[49] The NDPA is relevant to international health research as it helps to protect the data of participants that are collected, stored, processed or sent to another country for further research or processing.

4.2. National Information Technology Data Agency Guidelines

The National Information Technology Data Agency Guidelines establishes the National Information Technology Data Agency (NITDA) to promote and develop the use of information technology in Nigeria. The Agency is mandated to formulate guidelines for the 'collection, storage, processing, management, operation and technical controls of information'. It is expected that all individuals and organisations that 'control, collect, store and process personal data' of Nigerians comply with these guidelines. According to section 2 of the NITDA guidelines, personal data collection and processing must be done with the utmost consideration of the privacy of the research participants. It also mandates obtaining consent from the research participants before data is collected and processed.

4.3. National Code of Health Research Ethics

The National Code of Health Research Ethics (hereinafter referred to as 'the Code') was drawn up by the National Health Research Ethics Committee (NHREC) in 2007. The Code, which adopts the principles in the revised Helsinki Declaration and other international and national ethical guidelines on health research,[50] applies to all health research conducted in institutions and which involves human participants.[51] Both therapeutic procedures and non-therapeutic procedures are permitted and regulated by the Code.[52] The Code establishes principles and guidelines relevant to health research in Nigeria and promotes minimum risks to participants of research as well as

[44] Nigeria Data Protection Act, 2023 s30(a-f).
[45] Nigeria Data Protection Act, 2023 s26.
[46] Nigeria Data Protection Act, 2023 s26.
[47] Nigeria Data Protection Act, 2023 s39.
[48] Nigeria Data Protection Act, 2023 s39(2).
[49] Nigeria Data Protection Act, 2023 41(1).
[50] Yakubu and Adebamowo, (n 40) 4.
[51] Obiajulu Nnamuchi, 'Biobank/genomic Research in Nigeria: Examining Relevant Privacy and Confidentiality Frameworks' (2015) 43(4) Journal of Law, Medicine & Ethics 776-786.
[52] National Code of Health Research Ethics, Section A.

safeguards their rights and interests. It balances the needs of parties by seeking to ensure that the research is beneficial for everyone involved.[53] According to the Code, all research institutions should establish their own Health Research Ethics Committee (HREC) and when it is impracticable to do so, institutions are permitted to establish a cooperative agreement with external ones so long as the external HRECs are registered with the NHREC and meet stipulated geographical or proximity requirements.[54] The responsibilities of HRECs are spelt out under section E of the National Code. Some of these functions include reviewing research proposals and protocols before the commencement of research in order to ensure that all parties comply with the ethical guidelines of the Code and to ensure the safety and welfare of human research participants in Nigeria.[55] Usually, the HREC approves research proposals at their ordinary meetings except for accelerated review procedures. In such meetings, approvals are achieved when each case is discussed and there is a consensus among members or when a simple majority of members give their support.[56] HRECs can suspend research that is harmful to participants or contrary to ethical principles and regulatory frameworks.

In the case where the HREC of another country or institution approves research, such approval can be adopted by the HREC in Nigeria as long as the committee complied with the provisions of the Code and considered local circumstances. When there are discordant outcomes from two ethical committees, both committees should consult with each other to identify the conflicting issues and resolve them, thereafter giving a 'consistent single response' to the research parties.[57] NHRECs are expected to supervise the activities of HRECs and review their annual reports and establish norms and standards for health research relating to humans and animals as participants.[58] Their oversight duties also include examining consent forms, questionnaires, case report forms and other documents relevant to the research. The Code states that the Federal Government, acting through its organs and establishments, has the overall responsibility of protecting the welfare of Nigerian citizens, including those participating in research. To this end, the National Code recognises that apart from the NHREC and HRECs, other agencies of government in discharge of their duties according to law, may also perform regulatory functions in health research.[59]

4.3.1 Protection of Researchers in International Health Research Collaborations

Researchers in Nigeria are usually excited at the prospect of collaborating with researchers in other countries, especially developed countries. This is because of some benefits like funding and publications of such research in high impact journals which increases visibility for researchers and advances their academic career.[60] However, researchers may be exploited in international collaborative health research if they are not adequately protected and HRECs have been mandated to protect their rights and interests. Sometimes, such protection would include a review of the 'agreement between the sponsor(s), institution(s) and researcher(s) indicating rights to, ownership of and rights of access to data, resources, intellectual property and infrastructure generated in the

[53] Id, sec F.
[54] National Code of Health Research Ethics, Section C (f).
[55] Blessing Silaigwana and Douglas Wassenaar, 'Biomedical Research Ethics Committees in Sub-Saharan Africa: A Collective Review of Their Structure, Functioning, And Outcomes' (2015) 10(2) *Journal of Empirical Research on Human Research Ethics* 169-184.
[56] National Code of Health Research Ethics, Section e.
[57] Ibid, sec M(1)(e).
[58] Id, sec L.
[59] Id, sec M.
[60] Okonta, (n 3).

course of the research'.[61] The Code mandates that researchers in Nigeria should be able to publish their research and HRECs seek to protect this right by reviewing the agreement between parties that would enable the researcher to publish the results of the research while complying with ethical procedures and practices.[62] HRECs have also been directed to ensure that researchers in international collaborations do not bow to undue pressure from other parties and are not exposed to situations that restrict the enjoyment of their 'legal rights, freedoms and obligations under Nigerian law to pursue his/her research activities'.[63] In international collaborative research, researchers who apply to HRECs for approval of their research must be sufficiently qualified enough to work as principal investigators.[64] This requirement is a form of protection for local researchers because it keeps them in control and enables them advocate for modifications to the research, where necessary. Furthermore, Nigerian researchers who are principal investigators are in a better position to protect the rights of participants since they understand their culture and needs more than the foreign researchers.[65] The researchers must also be affiliated with 'a registered institution in Nigeria that is capable of carrying out the proposed research.'[66]

4.3.2. Protection of Participants in International Health Research Collaborations

HRECs must also protect participants of health research and one way of doing this is to ensure that all consent processes include all relevant information about the researchers so that they can be contacted by the participants, HRECs, the NHREC and institutional officials, when necessary.[67] Also, the consent process shall include the name and other details of the chairman of the HREC that gave approval for the conduct of the research and other individuals that the participants may want to contact for the purpose of increasing existing knowledge about the research.[68] Participants should be provided with medical treatment and adequate compensation for injuries they experience from the research and whether this is necessary and the extent to which this would happen is to be determined by HRECs.[69] The medical care should continue for a period of time after the research has been completed, depending on the nature of the injury, the research, and the intervention(s). When deemed appropriate, the HREC may require that researchers and the research sponsors make health insurance available to participants to adequately compensate for injuries encountered in the course of the research.[70] The Code specifies that research participants must not be requested to waive their legal rights in any situation including the right to legal redress for the harm they experience during research.[71] Participants who think that an ethical or scientific standard has been breached in the course of research should lodge a complaint to researchers, HRECs, institutional officials or the NHREC. HRECs must investigate such complaints and upon completion, send a report and the decision extract to all parties involved in the research within 3 months from the filing of the complaint.[72] The investigator must explore the likely causes of harm to the participants

[61] National Code of Health Research Ethics, Section R(1)(a).
[62] National Code of Health Research Ethics, Section S (2) i, ii.
[63] National Code of Health Research Ethics, Section S (5).
[64] Section M(3)a.
[65] Jeremy Sugarman and Participants in the Partnership for Enhancing Human Research Protections Durban Workshop 1, 'Ethical Oversight of Multinational Collaborative Research: Lessons from Africa for Building Capacity and For Policy' 2007 3(3) *Research Ethics* 84-86.
[66] National Code of Health Research Ethics, Section M (3)i.
[67] National Code of Health Research Ethics, Section S (1)i
[68] Section S (1) ii.
[69] Section S (1) iii.
[70] Section S (1) iv.
[71] Section S (1) v.
[72] Section S (1) vi-vii.

in the course of research and take measures to curb such circumstances, including sending reports to the sponsors, HRECs, NHREC and to NAFDAC, if such research is related to drugs testing.

A method of protecting research participants is through the establishment of a detailed and comprehensive consent process. The Code describes informed consent as a necessity for any research that would be conducted ethically and specifies the steps to obtaining a valid consent before research commences. The consent process must be designed in accordance with the type of research, the type of persons that would participate in the research and the expected risks. The consent form must not exceed 8 pages to avoid misinterpretation of terms and 'unnecessary verbiage, legalisms, jargons, and truth dumping'.[73] The consent document must contain the following: research title, names and affiliations of researchers, research sponsor, purpose and procedure of research, nature of the participation of each participant and approximate total number of participants that would be involved in the research, duration of research and involvement of participants as well as risk, cost and benefit to the participant, confidentiality protection, and voluntariness statement.[74] The consent document should also specify whether upon the completion of the research, benefits gained would be shared among researchers and if this would also extend to research participants.[75] The Code expands the provision of the National Health Act which states that the consent of participants of research must be obtained in writing. Thus, the Code provides that those who cannot express their consent by signing the required forms can thumbprint with witnesses present or use witnessed audio recording.[76] Sometimes, researchers would have to start another consent process while the research is still ongoing and the HREC determines circumstances that fall into this category.[77]

HRECs have been mandated to maintain confidentiality of information concerning research participants that they are privileged to discover as members of HRECs. Confidentiality is a perpetual obligation and continues even after membership at HRECs expire.[78] Research is only considered as ethical when participants are accorded respect and this must be evident from the start of the process when they are approached with the offer of participation, to the completion of the research. An aspect of respect involves treating participants as partners and informing them of developments in the research that may affect their health and wellbeing. Respect also includes protecting the welfare of research participants which means that the research must be carefully implemented so as not to expose them to extreme and unnecessary risks. Negative or detrimental effects of such research must also be disclosed to HREC and measures must be taken to prevent a re-occurrence.[79] The Code states that transparency is an important element for ethical research that is concerned about the welfare of participants. Thus, the 'goals, risks, benefits, alternatives to participation and voluntariness' of the research should be clearly spelt out to participants. Research that would protect the interests and safety of participants must comply with international standards that govern clinical and laboratory services including 'designing, conducting, and reporting clinical trials.'[80] Research should improve the health of participants and the communities where they live and also contribute to knowledge.[81]

[73] Section F (f) 3.
[74] Section F (5).
[75] Section F (5) xvii.
[76] Section F(8).
[77] Section F (f) 8.
[78] Section D (i).
[79] Section g.
[80] Section j.
[81] Section F(a).

4.3.3. Materials Transfer Agreement

Transfer of samples to other countries is viewed with caution by HRECs because of the inequality in power relations between countries and the potential harm such transfer could cause to individuals and communities in LMICs.[82] The Code thus permits the transfer of samples from human participants from Nigeria to other countries on the condition that parties sign a Materials Transfer Agreement (MTA). The MTA is expected to provide details concerning 'the type of materials, anticipated use, location of storage outside Nigeria, duration of such storage, limitations on use, transfer and termination of use of such materials subject to any law, regulations and enactment in Nigeria'.[83] This agreement helps to safeguard the rights of researchers in Nigeria and regulate the country's human and natural resources and their legitimate use. It also aims to ensure that human participants, either individuals or communities, are not exploited and harmed in the course of the research. All parties involved in the research including 'local and international principal investigators, heads of local institutions, research sponsors' are thus expected to sign the MTA.[84] HRECs will protect researchers and participants of research by reviewing the MTA to ensure uniformity with the specified objectives of the research, the informed consent documents and the principles identified in the Code. The NHREC also receives a copy of the MTA for its record after which the HREC will give its final approval to such research. Notwithstanding the MTA, research participants or communities have the right to withdraw from research whenever they deem fit. They can also request for the withdrawal of their data or samples from research as long as such samples have not been processed or used already, as withdrawal at that stage may affect the 'scientific validity of the research' and other participants.[85]

4.3.4. Protection of Communities Participating in Collaborative Health Research

Another important aspect of respect to participants that is mandated by the Code is engagement with communities where the research is to be conducted.[86] Akondeng and others, define community engagement (CE) in research as 'a process of inclusive participation that supports mutual respect of values, strategies and actions for authentic partnership of people affiliated with or self-identified by geographic proximity, special interest or similar situations to address issues affecting the well-being of the community of focus'.[87] CE has been identified as 'the major determinant of successful uptake of research, innovation and intervention'.[88] CE in health research in sub-Saharan Africa developed more in the 2000s during the human immunodeficiency virus (HIV) trials. HIV activists protested against the pre-exposure prophylaxis (PrEP) trials in Cambodia and Cameroon, stating that they did not sufficiently benefit from the trials despite the risks they took.[89] A study conducted by Anane-Sarpong and others, reveal that some communities in Africa place a lot of importance on obtaining the consent of elders before significant activities, including the collection and sharing of data would occur and permission from the government or

[82] Yakubu et al., (n 10) 13.
[83] Section n.
[84] Section n(1).
[85] Section f(g).
[86] Section g.
[87] Claudine Akondeng, et al. 'Community Engagement in Research in Sub-Saharan Africa: Approaches, Barriers, Facilitators, Ethical Considerations and The Role of Gender–A Systematic Review Protocol' (2022) 12(5) *BMJ open* e057922.
[88] Ibid.
[89] Samantha Vanderslott et al., 'How can Community Engagement in Health Research Be Strengthened for Infectious Disease Outbreaks in Sub-Saharan Africa? A Scoping Review of the Literature' (2021) 21(1) BMC Public Health 633.

its institutions, is not sufficient.[90] Such engagement before the commencement of research, builds trust, mutual respect and increases the willingness of the community to participate in the research, which would ultimately help in tackling their health challenges. Researchers would also be aware of the peculiarities of the community, their socio-cultural values and matters that are of utmost concern to residents.[91] Communities are also more willing to be a part of future studies and experiments related to healthcare.[92]

Researchers must uphold ethical values while engaging with the community and must include marginalised groups in the research project.[93] Dickert and Sugarman identify four ethical goals of CE to include: 'enhancing protection, enhancing benefits, creating legitimacy, and sharing responsibility'.[94] CE should not be a single occurrence for the whole period of research but should include constant and frequent engagement all through the phases of research, that is, from the preliminary planning stages to the completion of the research and publication of results.[95] To protect communities participating in research, HRECs in some circumstances, review the document containing the agreement between sponsor(s), institution(s), researcher(s) and the community, which clearly indicates that adequate CE took place.[96] HRECs request for this document when they have found the research approvable but require that the community is approached and engaged before the research starts. In such cases, the research would not be allowed to continue if the CE is unsuccessful. In certain circumstances, a community advisory board (CAB) would have to be established by the study investigators with input from the community. The CAB, which consists of community members, researchers and non-community members with expertise or knowledge in the research field, is saddled with the responsibility of giving community members the opportunity to express their opinions on the ethical issues that may arise during the course of research. The CAB meetings is also an avenue to offer guidance to ensure an effective process and to disseminate information concerning the research to members of the community. Members of communities should know if there would be benefits they would receive upon the successful completion of the research and the nature of such benefits should be clearly described to avoid 'unrealistic expectations.'

5. Protection of Researchers and Participants in Biobanks and Genomic Research

Biobanking has been defined as: 'structured resources that can be used for the purpose of genetic research and which include (a) human biological materials and/or information generated from the analysis of the same and (b) extensive associated information'.[97] Biobanks serve as a platform for

[90] Anane-Sarpong E et al., 'Application of Ethical Principles to Research Using Public Health Data in the Global South: Perspectives from Africa' (2018b) 18 Dev World Bioethics 98–108.
[91] Akondeng, (n 87) e057922.
[92] Reynolds L, Sariola S. 'The Ethics and Politics of Community Engagement in Global Health Research' (2018) 28 *Crit Public Health* 257–268.
[93] Lucy Carter et al., 'The Principles and Practices of Ethical Community Engagement' *Resources to Support Engaging for Impact. Canberra: Australian Centre for International Agriculture Research (ACIAR)* (2019): 2020-09.
[94] Neal Dickert and Jeremy Sugarman, 'Ethical Goals of Community Consultation in Research' (2005) 95(7) American Journal of Public Health 1123-1127.
[95] Ahmed SM and Palermo AG, 'Community Engagement in Research: Frameworks for Education and Peer Review' (2010) 100(8) Am J Public Health 1380–1387; Kolopack PA et al, 'What Makes Community Engagement Effective? Lessons from the Eliminate Dengue Program in Queensland Australia' (2015) 9(4) PLoS Negl Trop Dis. e0003713.
[96] Section s (4).
[97] Laura Annaratone et al., 'Basic Principles of Biobanking: From Biological Samples to Precision Medicine for Patients', (2021) 479(2) Virchows Archiv 233-246.

enabling the sharing of samples and data for research, which will ultimately accelerate research on disease treatment and lead to improved health outcomes.[98] Biobanking and genomic research has increased the rate of collaborations between researchers in different countries. It also ensures less difficulty in the re-use of samples and data for secondary research.[99] However, sharing data and samples in genomic research via biobank platforms raises a number of legal and ethical challenges.[100]

The Human Hereditary and Health in Africa (H3Africa), an initiative created by the United States National Institute for Health and the Wellcome Trust in the United Kingdom, made biobanking available in Africa by providing repositories in South Africa, Nigeria and Uganda. The biorepository located in Nigeria's capital city, Abuja, known as the Institute of Human Virology Nigeria H3Africa Biorepository has been stated to be the most visible biobank in Nigeria.[101] Genomic research and biobanking have increasingly been identified as a crucial method of improving knowledge on the nature of diseases and contributing to the success of research, with a high increase in such studies being conducted on the African continent and in Nigeria.[102] Regulatory frameworks governing this important aspect of research is however just evolving.

To address the gap of inadequate legal framework governing biobanking and genomic research, the H3Africa Initiative developed an ethical framework to set standards for biobanking and genomic research and protect the rights and interests of parties. Issues related to unfair treatment of researchers during collaborations and other issues concerning participants, either as individuals or communities were considered in the ethical guidelines.[103] According to the H3Africa Initiative ethics framework, genomic research and biobanking initiatives in Africa must comply with four core principles including: promoting respect for African values and culture; benefitting Africans principally and then the global community; ensuring that African researchers and other stakeholders are actively involved in the study and promoting respect, fairness, equity and reciprocity between parties of the research.[104]

The establishment and operation of biobanks is the exclusive responsibility of the NHREC while research conducted with samples stored in biobanks are supervised by HRECs.[105] NHREC has exclusive responsibilities due to the few biobanks currently available in Nigeria which means that the subsequent establishment of more biobanks might change the oversight responsibility of NHREC.[106] NHREC issued a policy statement in 2013 to regulate relevant ethical issues and HRECs have been mandated to ensure that research that involve samples stored in biobanks 'reflect the highest ethical standards and provide adequate protection for research participants'.[107]

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[98] Yakubu et al., (n 10) 13.
[99] Jantina de Vries et al, 'Regulation of Genomic and Biobanking Research in Africa: A Content Analysis of Ethics Guidelines, Policies and Procedures from 22 African Countries', (2017) 18(1) *BMC Medical Ethics* 8.
[100] Yakubu et al., (n 10) 13.
[101] Tobi Olajide et al., 'Stroke Neuro-biobanking and Genomic Research in Africa: A Narrative Review' (2025) 61(1) The Egyptian Journal of Neurology, Psychiatry and Neurosurgery 14.
[102] Simisola O. Akintola, 'Legal Implications of Data Sharing in Biobanking Research in Low-Income Settings: The Nigerian Experience' (2018) 11(1) South African Journal of Bioethics and Law 15-19.
[103] Yakubu et al., (n 10).
[104] Id.
[105] National Health Research Ethics Committee of Nigeria (NHREC), Policy Statement on Storage of Human Samples in Biobanks and Biorepositories in Nigeria November 1, 2013 (PS1.02013), at 2; Nnamuchi, n (51) 776-786.
[106] Nnamuchi, n (51) 776-786.
[107] National Health Research Ethics Committee of Nigeria (NHREC), Policy Statement on Storage of Human Samples in Biobanks and Biorepositories in Nigeria November 1, 2013 (PS1.02013), at 1,

5.1. Broad Consent and Blanket Consent in Genomic Research and Biobanking

Future use of samples and data are important components of genomic research and biobanking which means that the model used to obtain consent from participants must support the secondary use and sharing of data.[108] In Nigeria, the NHREC and the H3Africa Initiative ethics framework approve broad consent and not blanket consent. Broad consent refers to 'consent obtained from individual research participants at the time of sample collection that allows the use of their biological samples and associated data in primary research and for future research purposes'.[109] Thus, when samples stored in biobanks are needed for research at a later date, the consent of the donor would not be necessary again and the only ethical requirement would be an approval obtained from an HREC.[110] Sometimes, the donor would permit the samples to be used only for some specific diseases and prohibit other uses.[111] HREC may however order research participants to renew their consent during the course of research where substantial changes have been made to the conditions or procedures of the research.[112]

Blanket consent on the other hand, is consent obtained for research that is not defined in any manner and thus, such donated specimen or sample could be used for any type of research at a future date and shared without limitations.[113] Apart from Nigeria, the preference for broad consent appears to be growing internationally because it is believed that this consent model promotes the sharing of samples and data while at the same time, balancing the preferences of participants and their protection.[114] Zambia and Malawi on the other hand, prohibit researchers from obtaining broad consent from participants by prohibiting the collection of samples from individuals for unspecified future health research use or storage.[115]

Some scholars have criticised the use of broad consent for genomics and biobanking research. They, for example, question the notion of informed consent in research that is not specified, since consent can only be regarded as informed when all information concerning the act being consented to has been provided.[116] Proponents of broad consent argue that this model is not contrary to the principle of autonomy, as participants experience minimal risks during secondary research. They

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[108] Yakubu et al., (n 10); Akintola, (n 102) 15-19; H3Africa, 'Ethics and Governance Framework for Best Practice in Genomic Research and Biobanking in Africa' https://h3africa.org/wp-content/uploads/2018/05/Final-Framework-for-African-genomics-and-biobanking_SC-.pdf accessed 22 February 2026.

[109] Paulina Tindana and Jantina de Vries, 'Broad Consent for Genomic Research and Biobanking: Perspectives from Low-And Middle-Income Countries' (2016) 17(1) Annual Review of Genomics and Human Genetics 375-393.

[110] Gaia Barazzetti et al., 'Broad Consent in Practice: Lessons Learned from a Hospital-Based Biobank for Prospective Research on Genomic and Medical Data' (2020) 28(7) European Journal of Human Genetics 915-924.

[111] Tindana and de Vries (n 109) 375-393.

[112] Steinsbekk KS and Solberg B, 'Biobanks – when is Re-consent Necessary?' (2011) 4 Public Health Ethics 236–250.

[113] Oliver Mweemba et al., 'Use of Broad Consent and Related Procedures in Genomics Research: Perspectives from Research Participants in the Genetics of Rheumatic Heart Disease (RHDGen) study in a University Teaching Hospital in Zambia' (2020) 31(1) Global Bioethics 184-199.

[114] Francis Masiye et al., 'Stakeholder Views on Informed Consent Models for Future Use of Biological Samples in Malawi and South Africa' (2023) 24(1) BMC Medical Ethics 4.

[115] See the Malawi National Health Sciences Research Committee; General Guidelines on Health Research 2007, section 10; Zambia Health Research Act, 2013, provision 47(2)); Masiye et al., (n 114) 4; de Vries et al. (n 99) 8.

[116] Emma Bullock and Heather Widdows, 'Reconsidering Consent and Biobanking' in Christian Lenk, Judit Sandor and Bert Gordijn (eds) *Biobanks and Tissue Research: The Public, the Patient and the Regulation* (Springer, 2011) 111.

also state that broad consent makes the re-use of samples possible without going through the costly and tedious task of recruiting participants and collecting samples or data all over again.[117]

Some scholars have proposed an alternative model known as dynamic consent and this type of consent employs information and communication technologies to obtain the required consent from participants after informing them of the proposed use of their samples and data.[118] Although dynamic consent promotes the ease of obtaining consent from participants, this model has been applied more in high income countries than LMICs due to the insufficient availability of resources usually required to conduct an effective consent procedure.[119] Participants who are not educated would also find it difficult to use the required technology.[120]

5.2. Privacy

Privacy protection plays a major role while conducting research on data and samples stored in biobanks because when handled recklessly, people are hesitant to get involved with future or subsequent research.[121] The policy guidelines by NHREC permits both anonymization and de-identification of data. While anonymization involves the total and permanent removal of personal informal from the sample of an individual with no possibility of a future link between the donor and sample, de-identification is removing personal information from data but with the possibility of associating such information with the data in future.[122]

6. Concluding Remarks

The extant regulations in international health research collaborations have highlighted substantial provisions that would enable the protection of researchers and participants of health research in Nigeria. This is a step in the right direction which must however be accompanied with effective implementation. Some challenges would affect the successful implementation of these regulations in the research field. For instance, despite the importance of HRECs to ethical research, some institutions have not constituted HRECs which implies that researchers carry out activities without scrutiny and approval. The failure of institutions to constitute HRECs is primarily due to the lack of awareness of the regulations that mandate HRECs to be constituted, for example, the National Health Act and the NCHRE.

Furthermore, some HRECs in Nigeria lack adequate capacity to carry out their responsibilities and researchers lack adequate knowledge of ethical conduct in research due to the limited exposure to capacity building or training. Also, foreign researchers usually do not have sufficient knowledge of the rules applicable in Nigeria.[123] A study conducted by Ogunrin and others on the level of knowledge of the Code among researchers in four institutions in Nigeria revealed that only 30 percent of the 102 research participants were aware of the National Code. Twenty-five percent had a fair knowledge of the contents of the Code while only ten percent had an excellent knowledge

[117] Tindana and de Vries (n 109) 375-393.
[118] Kristin S Steinsbekk, 'Broad Consent Versus Dynamic Consent in Biobank Research: Is Passive Participation an Ethical Problem?' (2013) 21(9) European Journal of Human Genetics 897-902.
[119] Id.
[120] Tindana and de Vries (n 109) 375-393.
[121] Nnamuchi, n (51) 776-786.
[122] Christian Lenk, Judit Sandor and Bert Gordijn, 'Introduction' in Christian Lenk, Judit Sandor and Bert Gordijn (eds) Biobanks and Tissue Research: The Public, the Patient and the Regulation (Springer, 2011) 10.
[123] Chaudhry et al., (n 8).

of the code.[124] Until recently, capacity building on health research in Nigeria was not considered a priority because of 'weak educational, social, economic and health resources.'[125] Ignorance concerning the importance of capacity building and the benefits to researchers and participants is another reason. Moreover, some HRECs experience operational restrictions due to inadequate funds.[126]

It is thus recommended that HRECs and researchers undergo trainings to increase awareness of frameworks and ethical guidelines in health research, including genomic and biobanking research. This would enable researchers to be more aware of the procedures to obtain approval before they commence research with international colleagues. It would also improve the ability of HRECs to effectively review proposals.[127] Capacity building would help protect researchers and participants better, especially as innovative technologies are increasing and would have an effect on research.[128] Jeremy Sugarman et al, adds that trainings must consider the issues peculiar to Nigeria and address these issues.[129] Ogunrin and others, identify online training as one of the avenues to facilitate an ethics research training. In that study, 45 participants were trained to increase their knowledge of the Code and its provisions concerning ethical research in Nigeria. At the end of the online course, 97.8% of the participants agreed that the training increased their knowledge of ethical research in Nigeria.[130] Ogunrin and others, identify other training methods to include: seminars, distributing copies of the Code to the public and teaching undergraduate medical students the principles of ethical conduct in research.[131] Trainings conducted should cut across the whole 'academic hierarchy' including junior and senior scientists. In some circumstances, samples are only sent to other countries for analysis because Nigeria does not have sufficient capacity to analyse them. The government of Nigeria should devote more resources and funding to health research in collaboration with private institutions so that samples can be analysed in the country without the need to send them out and thereby limiting risks to individuals and communities.

In accordance with the recommendation of the Declaration of Helsinki, more investment is needed to assist institutions establish HRECs, enhance their capacity, set up their offices and maintain their operations to enable them effectively protect the rights and welfare of researchers and participants of international health research.[132] Also, in accordance with the Code, researchers should be principal investigators to enable them contribute to decision-making and avoid exploitation. Leadership roles would also enable them protect participants because they are more conversant with their needs.[133] HRECs must ensure that proposals pending approvals must be

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[124] Ogunrin, Olubunmi A., Folasade Daniel, and Victor Ansa. "Knowledge of the Nigerian code of health research ethics among biomedical researchers in Southern Nigeria." *Journal of Empirical Research on Human Research Ethics* 11.5 (2016): 397-407.
[125] Ibid.
[126] Essack, Zaynab, et al. "Health Research Ethics in Southern Africa: Building Capacity and Cultivating Excellence." *Journal of Empirical Research on Human Research Ethics* (2025): 15562646251347549.
[127] Essack, Z., & Wassenaar, D. R. (2018). South African Research ethics committee review of standards of prevention in HIV vaccine trial protocols. Journal of Empirical Research on Human Research Ethics,13(3), 239–246.
[128] Ibid.
[129] Jeremy Sugarman and Participants in the Partnership for Enhancing Human Research Protections Durban Workshop 1. "Ethical oversight of multinational collaborative research: lessons from Africa for building capacity and for policy." *Research Ethics* 3.3 (2007): 84-86.
[130] Olubunmi A. Ogunrin et al., 'Development and pilot testing of an online module for ethics education based on the Nigerian National Code for Health Research Ethics' (2013) 14(1) BMC Medical Ethics 1.
[131] Ibid.
[132] Silaigwana and Wassenaar, (n 55) 169-184.
[133] Obiora, (n 9).

promptly but carefully considered so that medical interventions would be swiftly initiated and to ensure that foreigners are not discouraged from collaborating with their colleagues in Nigeria.[134]

In conclusion, international collaborations are beneficial to populations but they must not cause harm to participants of such research or lead to the exploitation of researchers in Nigeria. To protect both parties, and maintain trust in research processes, ethical guidelines established in Nigeria must be applied to research activities. The Code contains comprehensive provisions protecting researchers and participants of research and it would improve the welfare of parties if it is efficiently implemented. HRECS are instrumental to effective protection and NHRECS and other appropriate authorities in Nigeria must ensure that all institutions whose members conduct research establish these committees and support their smooth running.

[134] Yakubu, Aminu, et al. 'Perceptions of Policymakers and Ethicists on Ethical Considerations in the Conduct of Research During Disease Outbreaks in Nigeria' (2024) 9 Wellcome Open Research 252.