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Knowledge and Practice of Research Ethics among Biomedical Researchers in Southern Nigerian Tertiary Institutions

Florence Olu Ogunrin[1], **Olubunmi A. Ogunrin**[2*] **and Bobbie J Murray**[3]

[1]*Senior Lecturer, Department of Business Administration, Faculty of Management Sciences, University of Benin, Benin City, Nigeria*

[2]*Consultant Physician and Neurologist, Neurology Unit, Department of Medicine, University Teaching Hospital, Benin City, Nigeria*

[3]*Human Protections Administrator, US Army Command and General Staff College, Fort Leavenworth, Kansas, USA*

[*]**Corresponding author:** Olubunmi A. Ogunrin, Consultant Physician and Neurologist, Neurology Unit, Department of Medicine, University Teaching Hospital, Benin City, Nigeria, Tel: 234-80-23344044; E-mail: bunmifunmi@hotmail.com

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Abstract

Objective: The knowledge and application of ethical principles to the conduct of human subjects' research is crucial to the integrity of the research industry. This study sought to assess the knowledge and practice of research ethics among biomedical researchers in research institutions in southern Nigeria.

Methods: Four tertiary biomedical research institutions from the three geo-political zones situated in the southern part of Nigeria were selected using a stratified random sampling technique. Research participants were then selected by purposive sampling from these institutions. The knowledge and practice of research ethics among the study participants were assessed with a pre-tested structured questionnaire. Statistical analysis was done with Stata version 10SE.

Results: A total of 102 biomedical researchers (66 males and 36 females) with a mean age of 39.8 (SD 7.0) years participated in the study. Forty-five percent knew that ethical review of research is for the protection of research participants from harm though sixty-four percent had attended at least one training seminar in research ethics. About fifteen percent knew of any international ethical guideline. Approximately eighty-five percent agreed that independent ethical review of protocol is important but only forty-eight percent received ethical approval for their research.

Conclusion: The knowledge and practice of research ethics is inadequate among Nigerian biomedical researchers. Attendance at ethics seminar did not reflect knowledge and practice of research ethics. The knowledge and practice of research ethics need improvement. The independent review of research protocols must be obligatory.

Keywords: Biomedical; Research ethics; Nigeria; Practice; Knowledge

Introduction

Ethics is basically 'doing what is right'. It tells us how we ought to act in a given situation and provide us with strong reasons for our actions [1]. Research ethics is concerned about ensuring that all research participants are protected from exploitation and other forms of harm [2]. Therefore, the knowledge of research ethics facilitates the application of information, facts, ideas or principles of ethics to human subjects' protection in research while its practice ensures that research is conducted according to established custom or habit and encourages the researcher to repeatedly do same in order to get better at it. However, we opined that the knowledge of ethics in research does not necessarily translate to practice, but the awareness of ethical principles enhances ethical practices provided there is an enthusiastic researcher. In research ethics, therefore, obligation of morality or practice of virtue ethics comes into play as researchers are expected to imbibe and demonstrate the highest quality of virtue by being ethical in their conduct.

The ethical conduct of research is mandatory for logical acceptability of the findings of a research but the lack of experience in application of ethical principles [3] and lack of ethical review of protocols have been reported among researchers in sub-Saharan African countries including Nigeria, and this has been attributed to the dearth of ethics training among researchers [4,5]. Furthermore, the poor ethics capacity also contributes to the lack of ethics review committees which have been reported in most of the African countries [6].

It is noteworthy that the sustenance of scientific research depends on public trust especially as the society, being a major stakeholder, has come to appreciate the role of scientific advancements in development. On one hand, however, the scientific community is gradually loosing public trust because of research misconduct and execution of unbeneficial scientific researches with lack of accountability on the side of biomedical researchers [7]. On the other hand, the respect for individual rights has become a constant concern, and its principles have become quasi-universal in research either as respect for the dignity of individuals or for the integrity of their persons, or for their personal autonomy through the rule of informed consent. Ethical practices therefore form the basis of public trust [8,9]. We are of the

opinion that the foundation stone of ethical practices in research is set on the soil of ethics education which is targeted at impacting knowledge and stimulating practice of ethical principles.

Research on human subjects continues to increase in resource poor sub-Saharan African countries [10,11], especially with growing collaboration between foreign and local researchers, with the concerns of an increasing demand for ethical regulation of research, need for competent ethical review committees and acceptable institutional capacity for ethical conduct of research. A prominent challenge is the need to protect the rights and welfare of research participants without neglecting integrity of research results and promoting high ethical standards among investigators. This concern may be resolved by improving the knowledge of investigators in research ethics. But first there is need to define the level of and identify the gap in knowledge and practice of research ethics among the local biomedical researchers. Hence, we designed this study to assess the knowledge and practice of research ethics among biomedical researchers in southern Nigeria with the specific goals of defining the magnitude of the gap in ethics knowledge and practice and hoping that the findings will serve as basis for ethics training in our research institutions.

Methodology

The research design was a cross-sectional descriptive study. The names of federal research institutions situated in the three geopolitical zones of southern Nigeria were obtained from the Nigerian National University Commission website. Four tertiary research institutions were selected using stratified random sampling technique. The first step involved using a ballot system to randomly select four states from the 16 states that constituted the three southern geopolitical zones. Then the second step involved random selection of four institutions from the list of eight institutions in the four states earlier selected in step one. One institution was randomly selected from the south west geo-political zone and three from the south-south. The study was limited to the federal tertiary institutions due to financial and logistic reasons.

Thereafter research participants were selected by purposive sampling technique from among biomedical researchers in the four institutions. All the biomedical researchers approached participated in the study. The study was conducted with the aid of a structured questionnaire containing questions to elucidate what the participants know about research ethics and how much of the key ethical procedures are practiced by them. The questions on 'knowledge' was focused on independent review of research protocols, informed consent, and distributive justice – fair selection of research participants, safety and data management and responsibility of the principal investigator. The questions on 'practice' focused on how many research they have conducted in the past and how many of their research protocols were sent for ethical review, and how often did they comply with dissemination or communication of their research findings in an ethical manner. Participants responded by ticking one of these options - Yes, Not sure, or No. Questions were scored equally; correct response was scored 2, 'not sure' scored 1, and incorrect scored 0. Demographic data (which include age, gender, area of specialization, highest degree obtained, professional status and institution) and information on attendance at ethics training or seminar were also obtained. The study protocol was approved by the University of Benin Teaching Hospital Research and Ethics committee. All the study participants gave informed consent.

Statistical analysis of data was done with aid of Stata SE version 10 (Stata Corp, Texas). Frequency distributions and percentages were used for descriptive statistics. Means and standard deviations were as measures of variation. The categorical variables were analyzed for significant differences using chi square distribution analysis while the strength of association between ethics training and knowledge and practice of research ethics was assessed with odds ratio, confidence intervals and Fischer's exact test.

Results

A total of 102 biomedical researchers participated in the study. Twenty (19.6%) participants were recruited from Benin City, 27 (26.5%) from Port Harcourt, 25 (24.5%) from Calabar and 30 (29.4%) from Lagos. There were 66 (64.7%) males and majority of the participants (43; 42.2%) were in the age range 31-40 years. Forty-two (41.2%) were faculty members and hospital consultants, 48 (47.1%) were senior residents and 12 (11.7%) were research officers. Sixty-four, comprising 62.7%, were in medically related specialties while the rest were either in surgically-related (29.4%) or laboratory-related (7.9%) specialties (Table 1).

Characteristics	Frequency	%
Age (years)*		
21-30	21	20.6
31-40	43	42.2
41-50	28	27.5
51-60	9	8.8
>60	1	0.9
Sex		
Male	66	64.7
Female	36	35.3
Professional status		
Consultants/clinicians	42	41.2
Resident doctors	48	47.1
Research officers	12	11.7
Specialty#		
Medical (clinical) specialty	64	62.7
Surgical (clinical) specialty	30	29.4
Laboratory-based	8	7.9

*Mean age = 39.8 years (SD 7.0; 95%, CI 37.9 – 41.8)

#Medical specialty includes Clinical pharmacology, Dermatology, Endocrinology, Neurology, Gastroenterology, Nephrology and Pulmonology; Surgical specialty includes General surgery, Radiology, Neurosurgery, Surgical oncology, Orthopedic surgery and Dental surgery

Table 1: Characteristics of study participants.

With respect to responses on knowledge of research ethics, 46 (45.1%) participants knew that the main objective of independent review of research protocols is to protect study participants from harm

but only 15 (14.7%) knew of at least one international ethical guideline. The most commonly mentioned international ethical guideline was World Medical Association's declaration of Helsinki (Table 2).

S/N	Questions	Responses*	Frequency (%)
1	List the three most important ethical considerations in any research project involving human participants?	Beneficence	10
		Compensation	4
		Consent	52
		Conflict of interests	2
		Privacy/ Confidentiality	48
		Safety	32
		Justice	20
2	List any three international guidelines or regulations that are supposed to guide the conduct of any research involving human participants?	Helsinki's declaration	15
		WHO-GCP	12
		CIOMS	4
3	Who is primarily responsible for ensuring that a research protocol is adhered to?	Principal Investigator	54
		RECs	50
		Participants' clinicians	18
4	Informed consent is not compulsory for conduct of research	Correct	68
		Not sure	10
		Incorrect	24
5	Researchers may disclose some information of their study participants to others in ways that are inconsistent with the understanding of the original disclosure without permission.	Correct	80
		Not sure	18
		Incorrect	4
6	Some research involving human subjects do not have ethical issues to be addressed.	Correct	44
		Not sure	16
		Incorrect	42
7	The data and safety monitoring board is responsible for ensuring that data are handled according to protocols to preserve the integrity of the research.	Correct	24
		Not sure	64
		Incorrect	16
8	For research to be ethical, it must be conducted in accordance with principles of good clinical and laboratory practices.	Correct	44
		Not sure	55
		Incorrect	3
9	The reason for ethical review of research is to protect study participants from harm and exploitation.	Correct	46
		Not sure	39
		Incorrect	17
10	The burden and benefits of research should be shared equally by study participants.	Correct	50
		Not sure	22
		Incorrect	30

*multiple responses allowed for questions 1 and 2; WHO-GCP – World Health Organization – Good Clinical Practice, CIOMS – Council of International Organization of Medical Sciences, RECs – Research Ethics Committees

Table 2: Frequency of respondents to questions on knowledge of research ethics (N=102).

In order of importance, the researchers indicated ethical issues of informed consent (50.9%), privacy which is expressed as confidentiality of participants' data (47.1%) and safety of study participants (31.4%) as important when conducting human subjects' research. The other ethical issues considered as important included justice (fair selection of participants), beneficence, compensation for study participants and conflicts of interest. Similarly, this trend was shown in the responses of the biomedical researchers to questions on research ethics. Most of the correct responses were obtained with questions on data confidentiality and informed consent while majority of the researchers were unsure of management of data and safety (Figure 1).

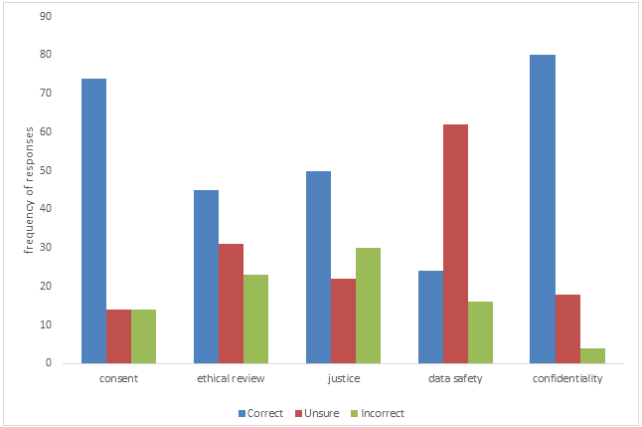


Figure 1: Responses of participants to questions on research ethics.

All the study participants were involved in human subjects' research. Eighty-seven (85.3%) agreed that independent ethical review of protocol is necessary before conducting research on human subjects but only 56 (54.9%) submitted their protocols for review while 49 (48%) received ethical approval for their research. Those who have published the findings of all their research works are in the minority (25.5%) while more than half (52%) have not published between 1 and 5 of their research projects (Table 3).

Fifty-two (53.9%) of the biomedical researchers had attended at least a seminar on research ethics which lasted for less than one week, however only 35 (34.3%) had received training on research ethics which lasted for more than a week. Most (27/35; 77.2%) of those who received ethics training attended courses lasting one to four weeks. Of those who attended, 30 (57.7%) gave more than half correct responses to questions on knowledge of research ethics. The attendance at ethics seminar or training did not significantly affect the knowledge of the study participants (OR 1.48; 95% CI 0.68-3.22; p=0.43). Likewise, the practice of research ethics was not affected by attendance at ethics seminar (OR 0.67; 95% CI 0.30-1.46; p=0.32).

	Frequency of responses (%)			
Number of research	**How many research works involving human subjects (not number of publications) have you participated in?**	**How many of the research works did you submit to a Research and Ethics Committee for approval?**	**How many of the research works were approved by the Research and Ethics Committee?**	**How many of your completed research have not been published?**
None	0 (0)	46 (45.1)	NA	26 (25.5)
1-5	64 (62.7)	42 (41.2)	38 (77.6)	53 (52)
6-10	14 (13.7)	10 (9.8)	7 (14.3)	12 (11.8)
11-15	6 (5.9)	0 (0)	0 (0)	11 (10.8)
16-20	10 (9.8)	2 (2.0)	2 (4.1)	0 (0)
>20	8 (7.9)	2 (2.0)	2 (4.1)	0 (0)
Total	102	102	49 (48)	102

Table 3: Responses to questions on practice of research ethics.

Discussion

This study revealed the inadequate knowledge and practice of research ethics among biomedical researchers conducting human subjects' research in southern Nigeria as revealed by high percentage of incorrect responses to questions on fair selection of research participants, data and safety management in research, and obligation of independent ethical review of research protocols. In addition, the findings showed poor practice of research ethics as reflected by dearth of submission of research protocol for ethical review and communication of research findings. The knowledge and practice of ethics in research were not affected by attendance at ethics seminars. These findings corroborated what has been observed by previous authors [4,12,13]. But the observation that attendance at ethics seminars did not significantly impact their knowledge was not in support of earlier reports that showed ethics training improved the knowledge of researchers [14,15]. This difference in observation could be due to the course contents of the training/seminars or methodologies employed by the trainers.

This study also identified areas of knowledge gaps, namely rationale for ethical review of protocols, data and safety management in research and fair selection of research participants. These are key ethical considerations which are crucial for risk and benefit analysis and protection of potential research participants from harm and exploitation. This finding is important as it draws attention to areas that require emphasis during ethics training sessions. Also, this observation reflected in the practice of the researchers. The poor understanding of the rationale for independent ethical review may explain why most of them did not submit their protocols for ethical review. It has been noted that identification of these gaps in knowledge and practice will facilitate training in research ethics and improve the knowledge of researchers in developing countries [16]. Additionally, one of the key capacities of stewardship in national health research system is the capacity to address ethical considerations in research projects [17], and no doubt this requires adequate knowledge of research ethics.

The knowledge of research ethics enables setting and monitoring of ethical standards, and monitoring and evaluating the health research system. In a study of 42 sub-Saharan African countries, increasing research capacity top the list of identified obstacles to collaboration in research between stakeholders [18]. To strengthen collaborations between local and foreign researchers and encourage robust ethical dialogue between stakeholders in the research enterprise, there is need to bridge the knowledge gap between the local and foreign partners. Integrity of multi-national research conducted at sites outside the developed countries depend largely on the local researchers who can only contribute explicitly to the research design and implementation, and remain alert to the potential conflicts of interest [19] if they are well grounded in research ethics [20]. So to address serious ethical concerns about internationally collaborative research, considerable efforts are being taken to develop research ethics capacity across the globe. This includes training researchers and those charged with ethical oversight in developing countries [19]. It is important to note that to develop effective ethics capacity, training must be sensitive to the types of research and ethical issues faced locally as local researchers may also function as principal investigators (PIs) thus placing the responsibility of protection of study participants on them thereby making adequate knowledge and practice of bioethics mandatory.

Since the purpose of research is to generate and contribute to generalizable knowledge that could benefit the present and future generations, some people and communities bear the burden of research. It is important that the research participants' safety, rights and welfare must not be compromised during the research. To ensure this protection, all human subjects research is subjected to independent ethics review [21]. The poor practice of ethical review of protocol observed in this study may expose potential research participants to harm and make research unethical. So for full potential benefits of health research to be realized, there is need for sound ethics review structures and functions within the developing countries, especially as the biomedical researchers sometime serve as members of ethics committees [13]. Continued training in research ethics will prevent violation of the rights of study participant's particularly vulnerable populations.

Several studies have shown the lack of research ethic committees in sub-Saharan African countries [22,23]. However as health-related research continues to increase in the sub-Saharan Africa there must be a proportionate rise in ethics capacity and setting up of functional health research oversight or governance structures and mechanisms particularly Research Ethics Committees [24]. The Nuffield Council for Bioethics, US National Bioethics Advisory Committee and the CIOMS emphasized capacity building in ethics for international collaborative research to train personnel in developing countries participating in such multi-national research. This in turn would help to create a pool of resource persons and researchers erudite in research ethics that will function as IRB or REC members in their respective countries thus allowing for independent ethical review of protocols and thereby curbing unethical practices [25-27].

This study revealed the poor knowledge and practice of research ethics among biomedical researchers in southern Nigeria, and the lack of significant effect of ethics training on their knowledge and practice. We recommend the review of contents of the modules of ethics seminars organized in the developing countries, and also making the ethical review of research protocols obligatory. In addition, researchers need to understand the importance of the ethical review process and make sure they practice it correctly while doing research.

References

1. Schüklenk U (2005) Module one: Introduction to research ethics. Dev World Bioeth 5: 1-13.
2. Emanuel EJ, Wendler D, Grady C (2000) What Makes Clinical Research Ethical? JAMA 283: 2701-2711.
3. Taiwo OO, Kass N (2009) Post-consent assessment of dental subjects' understanding of informed consent in oral health research in Nigeria. BMC Med Ethics 10: 11.
4. Ogundiran TO (2004) Enhancing the African bioethics initiative. BMC Med Educ 4: 21.
5. Hyder AA, Wali SA, Khan AN, Teoh NB, Kass NE, et al. (2004) Ethical review of health research: a perspective from developing country researchers. J Med Ethics 30: 68-72.
6. Kirigia JM, Wambebe C, Baba-Moussa A (2005) Status of national research bioethics committees in the WHO African region. BMC medical ethics pp. E10.
7. Harkness J, Lederer SE, Wikler D (2001) Laying ethical foundations for clinical research. Bull World Health Organ 79: 365-372.
8. Meslin EM, Garba I (2011) Biobanking and public health: Is a human rights approach the tie that binds? Hum Genet 130: 451-463.
9. Ursin LO (2010) Privacy and property in the biobank context. HEC Forum 22: 211-224.
10. Andanda P, Awah P, Ndebele P, Onigbogi O, Udatinya D, et al. (2011) The ethical and legal regulation of HIV-vaccine research in Africa: lessons from Cameroon, Malawi, Nigeria, Rwanda and Zambia. African J AIDS Res 10: 451-63.
11. Gordijn B (2014) Handbook of Global Bioethics. Springer publications, pp. 649-670.
12. Consortium HA, Rotimi C, Abayomi A, Abimiku A, Adabayeri VM, et al. (2014) Research capacity. Enabling the genomic revolution in Africa. Science 344: 1346-1348.
13. Adeleye OA, Ogundiran TO (2013) Knowledge of and Training in Research Ethics in an African Health Research Community. AJOB Prim Res 4: 44-50.
14. Ajuwon AJ, Kass N (2008) Outcome of a research ethics training workshop among clinicians and scientists in a Nigerian university. BMC Med Ethics 9: 1.
15. Ogunrin OA, Ogundiran TO, Adebamowo C (2013) Development and pilot testing of an online module for ethics education based on the Nigerian National Code for Health Research Ethics. BMC Med Ethics 14: 1.
16. Bhutta ZA (2004) Beyond informed consent. Bull World Heal Organ 82: 771-777.
17. Kebede D, Zielinski C, Mbondji PE, Sanou I, Kouvividila W, et al. (2014) Research and its governance in health research institutions in sub-Saharan African countries: results of a questionnaire-based survey. J R Soc Med 107: 55-69.
18. Zielinski C, Kebede D, Mbondji PE, Sanou I, Kouvividila W, et al. (2014) Research ethics policies and practices in health research institutions in 42 sub-Saharan African countries: results of a review by structured questionnaire sent to 847 health research institutions. J R Soc Med 107: 70-76.
19. Sugarman J (2007) Ethical oversight of multinational collaborative research: lessons from Africa for building capacity and for policy. Res Ethics Rev 3: 86-94.
20. Chima SC (2006) Regulation of biomedical research in Africa. Br Med J 332: 848-851.
21. Sun L (2013) Building Research Ethics Review Capacity in Swaziland: Health Research Ethics Workshop Report.
22. Kirigia JM, Wambebe C (2006) Status of national health research systems in ten countries of the WHO African Region. BMC Health Serv Res 6: 135.
23. Ndebele P, Wassenaar D, Benatar S, Fleischer T, Kruger M, et al. (2014) Research Ethics Capacity Building in Sub-Saharan Africa: A Review of NIH Fogarty-Funded Programs 2000-2012. J Empir Res Hum Res Ethics 9: 24-40.
24. Ouwe-missi-oukem-boyer O, Syntia N, Ntoumi F, Nyika A (2013) Capacity building in health research ethics in Central Africa: key players, current situation and recommendations. Bioethica Forum 6: 4-11.
25. (2002) The ethics of research related to healthcare in developing countries. Nuffield Council on Bioethics.
26. (2002) CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects Revised draft. United States of America.
27. (2001) Ethical and Policy Issues in International Research: Clinical trials in developing countries. US National Bioethics Advisory Commission.