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Compliance with research participant protection guidelines by Nigerian medical journals

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Abstract

Background Stakeholders in medical research have roles in ensuring that research participants are protected. Medical journals play gatekeeping roles in the responsible conduct of research. They help guard against the publication of findings of unethical research, such as those with compromised participant welfare. Nigerian medical journals are being created to support the growing number of research enterprises. In this study, we aimed to determine the compliance of Nigerian medical journals with guidelines on research participant protection.

Methods This was a descriptive cross-sectional study of Nigerian medical journals and articles. We used a checklist to obtain information on journal characteristics and the presence of recommendations from the International Committee of Medical Journal Editors (ICMJE) on the protection of research participants in the journal instructions to authors and articles. The data were analysed via IBM SPSS version 23.

Results We studied 40 journals and 350 journal articles. Thirty-one (77.5%) journals required ethical approval and the Declaration of Helsinki statement in their instructions to the authors, while informed consent was present in 26 (65.0%) journals; 6 (15.0%) journals had no participant protection guidelines. Forty-one (11.7%) articles complied with all three recommendations on research participant protection, whereas 60 (17.1%) articles did not. Ethical approval was most common in 268 (76.6%) articles, whereas it was least common in statements on the Declaration of Helsinki in 50 (14.3%) articles. The presence of participant protection recommendations in instructions to authors was not associated with compliance with these recommendations in published articles ($p > 0.05$).

Conclusion Although there is fairly good compliance of Nigerian medical journals with research participant protection recommendations, there are still gaps, which highlight the need for remedial measures.

Keywords Medical journals, Nigeria, Research participant protection, Informed consent, Ethical approval, Declaration of Helsinki

Introduction

The protection of research participants is paramount and underlies many regulations and laws on research ethics. It encompasses all the key principles of biomedical ethics, including beneficence, nonmaleficence, respect for autonomy and justice [1]. Beneficence and nonmaleficence ensure that benefit is maximised while risk of harm is minimised for the research participants. Respect for autonomy allows the participant to determine what

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happens to him/her in research, whereas justice ensures that participants receive a fair share of the benefits and risks of research. These principles underlie the stipulations of the Declaration of Helsinki on ethical principles for medical research involving human subjects [2]. Central to the role of research ethics committees is the protection of the research participants. Also, informed consent is an important ethical and legal imperative and ensures the protection of the rights and well-being of research participants [3, 4].

The International Committee of Medical Journal Editors (ICMJE) has established the 'Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals' [5]. These recommendations guide authors, editors and reviewers in ensuring best practices and high ethical standards in the conduct and reporting of accurate, reproducible and unbiased research and other material published in medical journals. ICMJE recommendations to ensure the protection of research subjects include (1) a statement that research for publication has been conducted in accordance with the Declaration of Helsinki on ethical principles for medical research involving human subjects, (2) the requirement of approval by an independent review body (ethics committee) and (3) written informed consent, which should be included in the instructions for the authors and the published article [5].

Various levels of compliance with participant protection guidelines have been reported in different parts of the world [6–22]. Medical research and its publication through journals are growing in Nigeria. There are no well-known and established existing bodies that regulate the activities of Nigerian medical journals. There is also a dearth of literature on how well these journals operate in compliance with publication ethics standards, especially with respect to research participant protection.

Considering the importance of participant protection at all stages of research, including publication, this study has become imperative. We aimed to objectively assess the compliance of Nigerian medical journals with research participant recommendations of the ICMJE.

Materials and methods

This was a descriptive cross-sectional study of Nigerian medical journals with an online presence and online journal articles published between January 2019 and December 2021 by Nigerian medical journals. The study was conducted between April and June 2023.

We performed an internet search for journals listed on the African Journal Online (AJOL) website, the Web of Science database on the Clarivate Analytics website, and the National Library of Medicine (NLM) Catalogue, with the term "Nigeria" as the country of publication. The selection of relevant medical journals was then performed manually. Medical journals were defined as publications that reported medical information to physicians and other health professionals [23]. For the purpose of this study, journals whose titles contained the terms 'medical', 'medicine' or 'health' or any of the medical specialties specified by the National Postgraduate Medical College of Nigeria [24], including Anaesthesia, Dental Surgery, Family Medicine, Family Dentistry, Internal Medicine, Obstetrics and Gynaecology, Ophthalmology, Orthopaedics, Otorhinolaryngology Head & Neck Surgery, Paediatrics, Pathology (chemical Pathology, Microbiology, Haematology, Anatomic Pathology), Psychiatry, Public Health and Community Medicine, Radiology, Surgery and Emergency Medicine, were selected.

Nigerian medical journals that have full-text research articles published online from January 2019 to December 2021 available on their websites and full-text research articles published online from January 2019 to December 2021 in Nigerian medical journals were included in the study. Letters to editors, editorials, abstracts, reviews, corrections, retractions, case reports and nonhuman studies were excluded.

Sample size determination: A census of all 40 eligible journals was performed. For the articles, after assuming a conservative expected proportion of 0.5 and a 5% precision, the minimum sample size was calculated via the Cochran formula for sample size in sampling for proportions and correction for a small population [25], resulting in 349 articles. From the 3825 eligible articles published in the journals during the period studied, 350 articles were selected by proportional stratified random sampling, with each journal taken as a stratum. Data were collected from the websites and instructions of the authors of the selected Nigerian Medical Journals and from articles published online. A checklist was used to obtain information on the type of journal, year of publication, and time interval between submission of the manuscript and date of acceptance and date of publication in the journal articles. It was also used to document the presence or otherwise of items on the ICMJE recommendation on the protection of research participants (part II E) [5] including (1) statements on adherence to the Declaration of Helsinki on research involving human participants, (2) approval by an independent ethics review committee and (3) informed consent in the journal's instructions to authors displayed on their websites and in the selected journal articles.

The data were entered into IBM SPSS version 23 (SPSS, Inc., IBM Corp., Chicago Illinois, USA), double-checked and analysed. Descriptive statistics such as the means, medians, percentages or proportions were used to present

data from the sample. The chi-square test was used as a measure of associations between variables. *P* values of less than 0.05 were considered statistically significant.

Results

Forty journals, comprising 23 (57.5%) general medical journals and 17 (42.5%) specialty journals, were studied. Additionally, 350 articles in Nigerian medical journals were studied, comprising 267 (76.3%) articles from general medical journals and 83 (23.7%) articles from specialty journals.

Among the 350 articles studied, 120 (34.3%) were published in 2019, 114 (32.6%) in 2020 and 116 (33.1%) in 2021. The mean submission-to-acceptance interval of the articles was 24.1 ± 21.2 weeks; the median was 16 weeks; and the range was 1–153 weeks. The mean acceptance to publication interval was 19.1 ± 16.6 weeks; the median was 14 weeks, ranging from 1–103 weeks. The mean submission-to-publication interval was 43.2 ± 28.0 weeks; the median was 39.5 weeks, ranging from 7–195 weeks.

All journals had instructions to authors displayed on their websites. Six (15.0%) journals did not conform to any of the components of the guideline on research participant protection according to the ICMJE in their instructions to authors, whereas 25 (62.5%) conformed fully to all three components of the ICMJE research participant protection guideline (Table 1).

The components include statements on adherence to the Declaration of Helsinki on research involving human participants, approval by an independent ethics review committee and informed consent.

Twenty-six (65.0%) journals conformed to the ICMJE guidelines on informed consent, whereas 14 (35.0%) did not conform. Considering the ICMJE guidelines on ethical approval and statement of the Declaration of Helsinki on research involving research participants, 31 (77.5%) journals conformed with the guidelines, whereas 9 (22.5%) did not conform with the guidelines in their instructions to the authors.

The ICMJE guidelines for research participant protection most frequently conformed to by the general medical journals were ethical approval by 18 (78.3%), whereas those most frequently conformed to by the specialty journals were statements on the Declaration of Helsinki by 14 (82.4%). There was no statistically significant association between the type of medical journal and compliance with any of the three guidelines on research participant protection ($p > 0.05$) (Table 2).

The ICMJE guidelines on research participant protection for articles have three components: statements on ethical approval, informed consent and adherence to the Declaration of Helsinki. The mean number of components was 1.59 ± 0.9, with a median of 2.0. Only 41 (11.7%) articles contained statements on all three components of the guidelines on research participant protection, 183 (52.3%) contained two, 66 (18.9%) contained one component of the guideline while up to 60 (17.1%) articles did not contain statements on any of the guidelines on research participant protection.

A total of 297 (84.9%) articles studied were from journals that specified ethical approval in their instruction to authors, whereas 53 (15.1%) articles were from journals that did not specify ethical approval in their instruction to authors. Of those articles whose journals specified ethical approval, 230 (77.4%) stated that ethical approval was obtained for their study. There was no statistically significant association between compliance with statements on ethical approval in articles and the presence of requirements for ethical approval in the journals' instructions to authors, $p = 0.36$ (Table 3).

Only 45 (15.0%) articles from journals that specified the Declaration of Helsinki statement in their instructions to authors had adherence to the Declaration of Helsinki indicated within the article. There was no statistically significant association between the requirement for reference to the Declaration of Helsinki in the journals' instructions to authors and the statement on compliance with the Declaration of Helsinki in the articles ($p = 0.35$) (Table 4).

Table 1 Total compliance with research participant protection guidelines in journals' instructions to authors

No. of components conformed to	No. of journals	%
0	6	15.0
1	4	10.0
2	5	12.5
3	25	62.5
Total	40	100.0

Table 2 Compliance with research participant protection guidelines by type of journal

Guideline	General medical No (%)*	Specialty No (%)**	X^2 (*p* value)
Ethical approval			0.018 (1.00)
Yes	18 (78.3)	13 (76.5)	
No	5 (21.7)	4 (23.5)	
Declaration of Helsinki			0.399 (0.707)
Yes	17 (73.9)	14 (82.4)	
No	6 (26.1)	3 (17.6)	
Informed consent			0.496 (0.521)
Yes	16 (69.6)	10 (58.8)	
No	7 (30.4)	7 (41.2)	

No = number of journals; *% based on 23 general medical journals; **% based on 17 specialty journals

Table 3 Ethical approval statement in articles vs ethical approval requirements in journals' instructions to authors

Ethical approval stated in articles	Ethical approval stated in journal's instruction		X^2 (*p* value)
	Yes No (%)	No No (%)	
Yes	230 (77.4)	38 (71.7)	0.827 (0.36)
No	67 (22.6)	15 (28.3)	
Total	297 (100.0)	53 (100.0)	

No = number of articles

Table 4 Declaration of Helsinki in articles vs declaration of Helsinki in journals

Declaration of Helsinki stated in article	Declaration of Helsinki in journal's instructions		X^2 (*p* value)
	Yes No (%)	No No (%)	
Yes	45 (15.0)	5 (10.0)	0.875 (0.35)
No	255 (85.0)	45 (90.0)	
Total	300 (100.0)	50 (100.0)	

No = number of articles

Table 5 Informed consent in articles vs informed consent by journals

Informed consent stated in article	Informed consent in journal's instructions to authors		X^2 (*p* value)
	Yes No (%)	No No (%)	
Yes	147 (64.8)	90 (73.2)	2.583 (0.11)
No	80 (35.2)	33 (26.8)	
Total	227 (100.0)	123 (100.0)	

No = number of articles

The statement on having obtained informed consent was contained in 147 (64.8%) of the articles whose journals had a requirement for informed consent in the instructions to authors. On the other hand, 90 (73.2%) of the articles from journals that did not require informed consent in their instructions to the authors had statements on having obtained informed consent within the articles. There was no statistically significant association between the requirement for informed consent in the journal instructions to authors and statements on obtaining informed consent in the published articles $p = 0.11$ (Table 5).

There was a statistically significant association between the type of journal and compliance of articles with ICMJE guidelines on ethical approval, with more articles from general medical journals, 213 (79.8%), than those from specialty journals, 55 (66.3%), conforming with ethical approval guidelines ($p = 0.011$). There was no statistically significant association between the type of journal and the compliance of the articles with informed consent or the Declaration of Helsinki ($p > 0.005$) (Table 6).

Table 6 Compliance of articles with research participant protection guidelines vs type of journal

Research participant protection item	Type of journal		X^2 (*p* value)
	General medical No (%)*	Specialty No (%)**	
Ethical approval			6.442 (0.011)***
Yes	213 (79.8)	55 (66.3)	
No	54 (20.2)	28 (33.7)	
Declaration of Helsinki			
Yes	41 (15.4)	9 (10.8)	1.053 (0.305)
No	226 (84.6)	74 (89.2)	
Informed consent			
Yes	185 (69.3)	52 (62.7)	1.276 (0.259)
No	82 (30.7)	31 (37.3)	

No = number of articles; *% based on 267 articles in general medical journals; **% based on 83 articles in specialty journals; ***statistically significant

Discussion

The results of this study show that there is an appreciable number of active Nigerian medical journals and published research articles. This reflects the growth of medical research in Nigeria. Encouragingly, the majority of the journals, 25 (62.5%), specified all three components of the research participants' protection guidelines in their instructions to the authors. However, 15% of the journals had no provision for any of the ICMJE research participant protection guidelines in their instructions to the authors. This suggests a vacuum in the gatekeeping role of an appreciable proportion of these journals, which could encourage unethical research practices. This study also underscores the need for enlightening journal editors on the importance of complying with these guidelines to equip their journals to carry out their role in the protection of research participants.

The compliance with ethical approval in instructions to authors of journals in the present study (77.5%) was similar to what was reported by Malicki et al. [7] among health sciences journals (74.0%). This finding is also similar to those of other studies of journals in the United Kingdom, the United States of America and Canada (76%) [26] and another study of specialty dentistry journals (77.7%) [15]. Higher compliance with ethical approval requirements than in the present study was

reported in a study of Indian biomedical journals [20] and in a systematic review of studies analysing instructions to authors [27], both of which were 84%. On the other hand, lower compliance rates than those reported in the present study were reported in studies of British journals (70%) [6], Indian journals (59%) [19], biomedical journals from Central European and East European countries (27% to 44.5%) [16] and another in Croatia (38%) [17]. Considering the immense value of medical research to society, the unacceptability of harm occurring to any individual who has volunteered to participate in research and the role of the research ethics committee in protecting the rights of research participants and ensuring that research is ethically sound, the acceptable compliance that would ensure the protection of all research participants should ideally be closer to 100% [3]. The need to sensitise medical journal editors on the importance of ensuring that ethical approval requirements are stated in all journals' instructions to authors is therefore highlighted here. This is even more critical, given that instructions to authors have been identified as the only means of communicating a journal's editorial standards to the researcher in most situations [8].

The compliance of journals with their instructions to authors with statements on the Declaration of Helsinki in the present study (77.5%) was greater than that reported by studies in other medical journals in different locations (9% to 71%) [18–22, 26, 28]. Compliance with informed consent in journals' instructions to authors by journals in the present study was lower than what was obtained for the other two guidelines, with approximately one-third of journals not making a requirement for informed consent. This failure of these journals to make an informed consent requirement implies that the facilitation of participants' autonomy and safeguarding of the rights and welfare of participants afforded by informed consent could be compromised in research published in these journals. The degree of compliance reported in the present study falls within the range (30–77%) reported in studies of different Indian, Brazilian, Croatian and British medical journals [8, 15, 17, 28–30].

These variations in compliance may be related to differences in the time and locations where the studies were conducted. Malicki et al. reported that the compliance of journals with publication ethics guidelines varies over time and across locations [27].

The present study revealed that there was no statistically significant association between the requirements of the research participant protection guidelines in the instructions to authors and the statements of these guidelines in the articles published in journals ($p > 0.05$). The majority of articles in journals that did not make a requirement for ethical approval (38, 71.7%) and informed consent (88, 71.5%) had statements on ethical approval and informed consent, respectively. This suggests that although the journals did not meet these requirements, authors on their own could comply with these ethical standards. However, leaving compliance with these standards to the discretion of the authors only affects the gatekeeping roles of journals in publication ethics and could provide room for unethical research practices and publications therefrom. It is therefore important that all journals clearly make a requirement in line with the ICMJE guidelines on research participant protection in their instructions to authors. The other aspect of this finding is that an appreciable proportion of articles published by journals with requirements on the three items on research participant protection did not conform to these guidelines [ethical approval (26.3%), informed consent (35.2%) and Declaration of Helsinki (85.7%)]. This suggests that these guidelines, though they are required by the journals, may not be considered and have no determinant role in the acceptance of articles for publication. This draws attention to the need for journals to both meet these requirements in their instructions to authors and ensure compliance by authors as part of the conditions for acceptance of manuscripts for publication. This will help ensure the protection of research participants by having researchers state their compliance with the guidelines on research participant protection in their articles, supported by the responsibility of the author in refraining from research and publication malpractices [31].

The finding in the present study that more than 1 in 6 articles did not contain any statements on having conformed to any of the three items in the ICMJE guidelines on research participant protection is worrisome. This is because it is probable that the associated research may not have ensured the protection of participants, which could render participants vulnerable to harm. It could be argued, however, that not making a statement in an article that these guidelines were followed does not necessarily mean that they were actually not conformed to in the conduct of the research. On the other hand, there is no way to know whether these guidelines were complied with except a statement is made in the articles for publication in that regard. Furthermore, the ICMJE requires that statements on having adhered to these guidelines be made in the manuscripts for submission [32]. Additionally, having statements made in the articles provides assurance to society that research has been ethically conducted and published, which has the value of engendering public trust in research.

The finding that the majority of the articles studied conformed to the ethical approval requirements could be considered encouraging. This is because research

ethics committee roles also include ensuring the adherence of research to the Declaration of Helsinki and providing informed consent [3]. Therefore, when a research ethics committee has reviewed and approved a study, it is probable that the other two items of the guidelines on research participant protection were adhered to, even when corresponding statements are absent in the articles. On the other hand, this would not offer maximal protection to participants in cases of fraudulently obtained ethical approval or approvals obtained from incompetent research ethics committees. It is therefore vital that the ICMJE guidelines on research participant protection are fully complied with. The compliance rates with ethical approval and informed consent in the articles of the present study were higher than those reported in other studies in Cameroon, India, China, Iran, Germany and the United Kingdom, which ranged between 1 and 71% for ethical approval; and between 7 and 66% for informed consent [9–14, 33–37].

The finding in our study that more articles from general medical journals than from specialty journals tended to conform to the ethical approval requirement suggests that editors of general medical journals could pay more attention to these guidelines in consideration of manuscripts for publication than their specialty journal counterparts.

In conclusion, although majority of the medical journals and journal articles studied complied with the ICMJE recommendations on human participant protection, a significant minority did not abide by these recommendations. This indicates a gap in the role of journals in the protection of research participants. Our study highlights the need for closer attention from all stakeholders in medical research publications in Nigeria to the improvement of compliance with research participant protection guidelines which will ensure the promotion of the welfare of research participants and continue to sustain the benefits of medical research to society. Continuing education and sensitisation of editors and authors on research ethics in general and the importance of compliance with research participant protection guidelines as well as closer monitoring of journal activities by regulatory bodies are recommended. The findings of this study could serve as an objective tool that could be useful for advocacy in support of increased attention to research ethics practice in medical journals and the role of journals in research participant protection. Future research could explore barriers to compliance with human research participant protection recommendations and ways to improve compliance among journals.

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Authors' contributions
AO and EE were involved in conceptualization and design of the study. AO did the acquisition of data. AA and EE did analysis and interpretation of data. AA and EE drafted the manuscript and revised the work. AA and EE approved the final submitted version of the work.

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Data availability
The data that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate
Ethical approval was obtained from the University of Nigeria Teaching Hospital Research Ethics Committee, Enugu, with reference to UNTH/HREC/2022/12/502. Consent to participate was waived. The confidentiality of the obtained information was ensured, and no identifying information from the journals, editors, or authors was used.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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