EVALUATING ETHICS APPROVAL AND INFORMED CONSENT IN SELECTED ONLINE NIGERIAN MEDICAL JOURNALS

Dr Joseph Ethagbe Alimasunya

(213569744)

MB ChB

Supervisor: Professor Douglas R. Wassenaar

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Declaration

I declare that this dissertation represents my own work, except for those where due acknowledgement is made, and that it has not been included in a thesis, dissertation or report submitted to this university or any other institution for a degree, diploma or other qualifications.

Signed … [redacted]

Dr Joseph Ethagbe Alimasunya

Signed… [redacted]……

Prof D R Wassenaar

(Supervisor)

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List of Abbreviations

AIPM – Annals of Ibadan Postgraduate Medicine

AJRH – African Journal of Reproductive Health

AJOL – African Journal Online

BREC – Biomedical Research Ethics Committee

CIOMS – Council for International Organizations of Medical Sciences

COI – Conflict of Interest

COPE – Committee on Publication Ethics

HANARI – Health InterNetwork Access to Research Information

ICMJE – International Committee of Medical Journal Editors

IRB – Institutional Review Board

JCMPH – Journal of Community Medicine and Primary Health Care

JMBR – Journal of Medicine and Biomedical Research

NJCP – Nigerian Journal of Clinical Practice

MSocSc – Masters in Social Science

NHREC – National Research Ethics Committee

NIH – National Institutes of Health

REC – Research Ethics Committee

SPSS – Statistical Package for the Social Sciences

SARETI – Southern African Research Ethics Training Initiative

SOP – Standard Operating Procedure

UKZN – University of KwaZulu-Natal

WMA – World Medical Association

WHO – World Health Organization

CHAPTER 1: INTRODUCTION

1.1 Overview and background information

This chapter provides an overview to this study. This was a quantitative, retrospective study which sought to determine the frequency of research ethics approval and informed consent reporting in selected online Nigerian medical journals.

The need to regulate research activities involving human subject participation led to the establishment of Institutional Review Boards (IRBs), also known as Research Ethics Committees (RECs) in most research institutions globally. It is a universal requirement that all biomedical research studies involving human subjects be reviewed by an independent REC/IRB (World Medical Association, 2013).

One of the fundamentals of research activities involving human participants, including identifiable human materials, data or information, is the provision for ethical protections. The Declaration of Helsinki (WMA, 2013) clearly states the need for researchers to obtain informed consent from study participants as one of the prerequisites that should be met in the study protocol before approval can be granted by an REC or IRB. Similarly, the Council for International Organizations of Medical Sciences (CIOMS, 2016) in its international guidelines has made provision for the ethical protection of participants involved in biomedical research activities.

In recent years there has been an increase in social and biomedical research activities throughout the world, with particular emphasis in developing countries where the disease burden is at its highest (Nyika, Kilama, Tangwa et al., 2009). With the increase in biomedical research activities involving human participants in developing countries, Nigeria is no different; there is an increasing need to publish and disseminate research findings in accessible regional and local journals.

Studies have been conducted among some western biomedical and health-related journals to examine compliance with adherence to the Declaration of Helsinki (2013). The International Committee of Medical Journal Editors working in conjunction with numerous biomedical journals have developed guidelines which require that "…when reporting experiments on human

participants, authors should indicate whether the procedures followed were in accordance with ethical standards of the responsible committee on human experimentation (institutional and national) and with Helsinki Declaration of 1975, as revised in 2000" (Schroter et al., 2006, p. 718–723). Most countries have developed and adhere to their own national framework for human subject research based on these guidelines (Tangwa, 2004).

There are no known empirical studies of Nigerian journals which assess the extent to which regional or national biomedical health related journals report adherence to existing research ethics guidelines; in particular regarding whether REC review and informed consent are expressly mentioned in publications reporting research which involves human participants. A study to evaluate the reporting of research ethics approval and informed consent in articles from samples of biomedical Journals in Nigeria may shed light on their reported compliance with national and international ethics guidance. Using a quantitative approach, a consecutive series of articles from five Nigerian online medical and biomedical journals publications were reviewed for reporting of research ethics approval and informed consent.

This study attempts to replicate a study by Schroter et al. (2006) which is reviewed more fully in the next chapter.

CHAPTER 2: REVIEW OF LITERATURE

2.1 Importance of research ethics approval and informed consent

Ethical principles governing research with human participants have evolved over the years. Several guidelines for ethical conduct of biomedical research have been published since World War II. These include the US Federal Policy for the Protection of Human Subjects or Common Rule (1979) and the Federal Regulations Common Rule (45 CFR 46) (1991, as revised 2018) on the protection of human subjects. Others include, the International Covenant on Civil and Political Rights (1966), the International Code of Medical Ethics of the World Medical Association (Declaration of Helsinki) (1948, amended in 1968, 1983, 1994, editorially revised in 2005 and 2006 and amended in 2017), the WHO Operational Guidelines for Ethics Committees that Review Biomedical Research (2000), CIOMS (2016). There are thus several international guidelines on the ethics of medical research. These guidelines aim to minimise the risk of exploitation or harm and promote the welfare and wellbeing of participants, wherever research involving human participation is undertaken.

In Nigeria, a national guideline and standard operating procedure (SOP), the Nigerian Regulatory Code for Human Subject Research, also known as the National Code of Health Research Ethics (2006) guides all research activities involving human participants.

The history of national ethical regulations of human subject research dates back to the 1980s, but these efforts were not sustained due to lack of sustained interest and funding as well as decades of military misrule and socioeconomic dislocation (Adebamowo et al., 2008). However, with the advent of civilian democratic rule in 1999 which coincided with increased international concern and attentions to unethical health research activities that occurred in developing countries, especially following the tragic outcome of Pfizer Trovan study in 1996 in Kano, Nigeria the need to strengthen

existing ethical regulations by institutions which already have RECs in place, and also setting up RECs by institutions which do not have across the country was emphasised (Adebamowo et al., 2008).

With this sustained effort, and following a presidential retreat on the health of Nigerians, it was strongly highlighted that Nigeria needed an ethics regulatory infrastructure for health research to meets its United Nations Millennium Developmental Goals targets (Adebamowo et al., 2008, p. 17). The National Health Research Ethics Committee (*NHREC*) was reconstituted and strengthened by the Federal Government of Nigeria, and backed by legislation for implementation (Adebamowo et al., 2008). The National Health Research Ethics Committee (*NHREC*) thereafter developed a national guideline and standard operating procedure, the Nigerian Regulatory Code for Human Subjects Research, also known as the National Code of Health Research Ethics (2006) to guide all research activities involving human subjects. The code outlines "the norms and standards that must be applied for the ethical review of research in Nigeria" (Adebamowo et al., 2008, p. 17).

Similarly, ethical principles relating to publication of research findings in studies involving human participants including identifiable human materials or identifiable data have been developed to ensure safety and enhance ethical protection for the participants. The establishment of the International Committee of Medical Journal Editors (*ICMJE*) and Committee on Publication Ethics (*COPE*) was to ensure that journal editors carry out their gatekeeping role by making sure that research submitted and published in their journals strictly conforms to the applicable ethical guidelines (*COPE*, 2004; Doherty & Van De Putte, 2000; *ICMJE*, 2004). The *COPE* guideline provides advice to editors and publishers on all aspects of publication ethics and, in particular, on how to manage cases of research and publication misconduct (*COPE*, 2004).

Research conducted on biomedical journals to assess the extent of adherence to these guidelines by journals has shown poor compliance with publication ethics despite being signed up to the *ICMJE* (2018) requirements which state that authors should expressly state that research ethics approval was granted and informed consent obtained for their research if it involves human participants. A study by Schroter et al. (2006) reports a temporal improvement in the reporting of ethical protections in major medical journals in the UK. This study compared the *British Medical Journal* and four other general medical journals in developed countries including the *Annals of Internal Medicine, Lancet, The New England Journal of Medicine* and the *Journal of the American Medical Association* in which an average of 69% reported research ethics approval and 53% reported informed consent. A similar study found 71% and 66% respectively in reporting of research ethics approval and informed consent in a leading anaesthesia journal (Myles & Tan, 2003), 57.53% and 70.78% and 50.68% for research ethics approval, informed consent, and both research ethics approval and informed consent reporting mentioned respectively for publications from Cameroon indexed on PubMed (Munung, Che, Ouwe-Missi-Oukem-Boyer, & Tangwa, 2011).

Also, a study conducted by Sumathipala et al. (2008) in Sri-Lanka found that documentation of research ethics approval and informed consent occurs in around 35% of research publications in international and local journals respectively. However, this indicates an increasing trend in documenting REC approval and informed consent by participants. Wu et al. (2019) in similar study of five leading international nursing journals from the *SCI Journal Citation Reports* between 2015 and 2017 show that 93.7% reported research ethics approval and 87.5% reported informed consent by participants.

However, these findings cannot be generalised to biomedical and health journals in Nigeria. There is no previous empirical evidence to assess Nigerian journals' compliance with such guidelines and adherence to the *ICMJE* guideline.

Biomedical journals can also contribute to the protection of human participants by putting in place a gatekeeping mechanism through which journal editors ensure that researchers comply with ethics guidelines (*COPE*, 2004; *ICMJE*, 2018). According to the World Medical Association (2000), journals have the obligation to either accept or reject publications based on strict adherence to existing ethics guidelines governing human research. However, many smaller journals (https://www.ajol.info/index.php/index/browse/country?countryId=156) are faced with challenges ranging from poor editorial skills and review processes, language, indexing system bias, constraints arising from poor resources, poor author pool, and lack of credibility, irregular publications as well as poor visibility (Chattopadhyay, Myser, Moxham, & De Vries, 2017; Gibbs, 1995; Ofori-Adjei, Antes, Tharyan, Slade, & Tamber, 2006). Similarly, due to their wider outreach and impact, most international journals also attract authors from developing countries (Ofori-Adjei et al., 2006). However, publishing in some open access high impact international journals is becoming increasingly difficult due to high open access costs, exchange rates and other research economic dynamics (Horton, 2003). In addressing these gaps, efforts are being made through the African Journal Partnership Program (https://www.ajpp-online.org/) which aims to strengthen African medical and health journals to provide a platform for African researchers to publish their findings, thereby reducing the disparity between publication opportunities in western dominated journal publication platforms and those in developing countries (Domiziana, 2017). This strategy aims to help researchers from low resourced African countries publish their research findings in

World Health Organization (WHO) and Health InterNetwork Access to Research Information (HANARI) funded journals at a much lower cost (Momen, 2003).

It is, however, noteworthy to state that for local/national journals to meet international standards of editing, publishing and protecting research participants there is also a need for adherence to international ethics guidelines related to publication, developed by ICMJE (2018) and COPE (2004). If these measures were implemented by all local journals, they could greatly enhance the growth and standard of ethically conducted health-related research, thereby contributing to generalisable knowledge in advancing the wellbeing of society and the body of science.

This study hopes to generate information that might inform biomedical and health journals about their level of adherence to ethical principles and requirements for local researchers and journals to mention ethics review and informed consent in empirical publications.

CHAPTER 3: METHODOLOGY

This chapter gives an overview of the nature of this study, the research design, procedures, data processing, management and analysis for the conduct of this study.

Data was collected randomly from five selected Nigerian biomedical and health journals (*African Journal of Reproductive Health, Journal of Community Medicine and Primary Health Care, Journal of Medicine and Biomedical Research, Annals of Ibadan Postgraduate Medicine and Nigerian Journal of Clinical Practice*) hosted on the African Journals Online (AJOL) over a 10-year period, 2007 to 2017. This is based on their consistency and volumes of publication series to meet the sample size of approximately 400 articles.

3.1 Study aims

The purpose of this study was to assess reporting of research ethics approval and informed consent for several study designs in five online Nigerian general (non-specialist) biomedical and health journals.

3.2 Main objectives

The main objectives of this study were to:

- Study the reporting of research ethics approval for studies published in the selected Nigerian biomedical online journals.
- Study the reporting of informed consent obtained from study participants in the selected Nigerian online biomedical journals.

3.3 The research questions

The study answered the following questions:

- How frequently is research ethics approval reported in original published Nigerian online biomedical research articles?
- How frequently is informed consent reported in original published Nigerian online biomedical research articles?
- Did any types of studies have more or less of the above two types of reporting?

3.4 Background to the research

This research was undertaken in fulfilment of the requirements for the award of Master's degree of Social Science (Health Research Ethics) of the South African Research Ethics Training Initiative (SARETI) at the University of KwaZulu-Natal.

This thesis covers the findings on five online published Nigerian health and biomedical journals hosted online on the African Journal On-line (AJOL) platform. The aim of the study was to assess whether studies reported receiving ethics clearance and report informed consent strategies for several study designs in five general originally published online biomedical and health journals in Nigeria.

This study attempts to replicate a study by Schroter et al. (2006) which reviewed "reporting ethics committee approval and patient consent by study design in five general medical journals".

3.5 Study design

This is a quantitative, retrospective study design. A consecutive series of research articles published in five different Nigerian Online Medical and Health Journals dated 2007 to 2017 were reviewed for the reporting of research ethics approval and informed consent. Research Ethics approval, informed consent and study type was recorded. The data were evaluated using simple descriptive statistics.

The sample frame and time include original research articles describing research on human participants or human tissue, published between January 2007 and December 2017, and made available and accessible through the AJOL online platform. This time frame was chosen so as to access more publications in order to meet the sample size for this study.

3.6 Sample size and sampling techniques

The sampled journals were from five different Nigerian medical and health research journals hosted online on the African Journal Online (AJOL) platform. Those selected for study were selected based on open access and their regular publication of consecutive research articles with human participants. Sample size aimed at approximately 400 articles based on the volume of publications by these journals under study within the stipulated study time frame 2007–2017, ideally selecting the same number of articles (*n*=80) from each journal.

- Inclusion criteria: Articles from one of the five listed journals that report on a health-related research study involving human participants.
- Exclusion criteria: Articles from journals other than the 5 listed; systematic reviews, meta-analyses, ecological studies, review articles, secondary analysis of published data, clinical audit or quality improvement, laboratory-based studies not using patients or patient

material review articles, theoretical articles, articles reporting on organisms that do not derive from human participants, articles reporting on animal studies.

3.7 Data collection

Electronic versions of each original article were obtained and the study design identified and assessed for eligibility for the study. Only original research articles describing research on human participants or human tissue requiring research ethics approval and informed consent was eligible for study. Articles were categorised into one of several typical study designs namely; randomised controlled trial, case-control, cohort, cross-sectional, case report, case series, qualitative, observational studies, analysis of data collected on routine basis such as in surveillance studies. Articles describing more than one study design was defined according to the main focus of the research article (see Appendix 1).

Each selected article was read in detail and information extracted (see Appendix 1) and the following categories of information were collected verbatim or in a simple binary (yes/no) format (Schroter et al., 2006):

- Journal name
- Study design (randomised controlled trial, case–control, cohort, cross-sectional, case report, case series, qualitative, analysis of data collected on routine basis such as in surveillance studies).
- Whether the article mentioned whether the study was approved by an REC or IRB
- Whether the article mentioned whether participants gave informed consent

A standard data capture sheet was designed in line with the above information as outlined (see Appendix 1).

3.8 Data analysis

The data obtained were captured into SPSS. Multivariable logistic regression was used to examine differences between failure to mention research ethics approval and failure to mention informed consent. The dependent variables are mentioning of research ethics approval for the study and informed consent by authors in articles. The independent variables are the study design, the name of journal and whether the study included a vulnerable population. A test for the overall differences was conducted between study design and between journals by using the likelihood ratio tests, such as Odds Ratios (OR), with 95% confidence intervals.

3.9 Dissemination of findings

Findings will be published in a research thesis and submitted to peer-reviewed journals. They will also be communicated to the various journal editors involved either through a simple feedback sheet or a seminar or executive summary or during one of their editorial meetings with their permission.

3.10 Validity, reliability and rigour

According to Hammersley (1990, p. 57), validity in research is defined as "…truth: interpreted as the extent to which an account accurately represents the social phenomena to which it refers". Cook and Campbell (1979) developed a taxonomy of threats to research validity, namely: statistical conclusion validity; construct validity; external validity and internal validity. Internal validity refers to whether the inferences made from the collected data are accurate (i.e. valid) and external validity to the ability to generalise from the results of the study to other environments and populations" (Selormey, 2015, Frimpong 2016 & Kirimuhuzya, 2020).

For both practical and logistical reasons, it was not possible for the researcher to incorporate all of the above strategies into this study. However, the strategies of peer review of methods (with fellow researchers doing the same topic), as well as clarifying researcher bias will be considered in the design and conduct of this study from the outset. The variables studied are overt and categorical, and likely to be reliably identified and coded. Furthermore, the researcher identified the specific problem of 'anecdotalism' – the inclination of some researchers to convince both themselves and their readers that the findings of their study are genuine results, based on a critical unbiased analysis of the data collected and not based on a few 'well-chosen examples – as a potential threat to the overall validity of the study (Frimpong, 2016; Kirimuhuzya, 2020; Selormey, 2015; Silverman, 2006). The internal and external validity of this present study were identified by the researcher during the design process. The researcher acknowledges Cook and Campbell's (1979) taxonomy of threats to validity and recognises that a) because the research is a desk review, carried out on specific documents kept for specific purposes with a specific group of people working in a specific environment, it is possible that the study will not return results that are high in external validity (i.e., that it will not be possible to generalise the results to other populations and/or to other environments) and b), that because the sample population was primarily selected using purposive methods, the element of randomness is not present in the selection process. This may, therefore, impact upon the internal validity of the study's results (Frimpong, 2016; Kirimuhuzya, 2020; Selormey, 2015). The sample will represent the volume of published articles by selected journals and archived on the AJOL platform from 2007–2017.

Stenbacka (2001, p. 557) explained that reliability is a concept to evaluate quality in a quantitative study with the "purpose of explaining" which relates to the concept of good quality research. To ensure this, the researcher took the necessary step in line with the Schroter et al. (2006) study by

ensuring equivalence in finding using the inter-rater reliability test (Heale & Twycross, 2015). This test compared the consistency of the current research findings with those of Schroter et al. (2006).

3.11 Anticipated problems/limitations

No major problem was encountered during this study as the journals were hosted on the AJOL platform, and accessible to the public.

3.12 Strength of the study

This research is the first known study that examined the reporting of ethics protections in published articles in biomedical journals in Nigeria. Its strengths are hopefully that it will review articles published over a 10-year period and will not be focusing on one study design, medical specialty or patient population. As with previous studies in developing and developed countries (Schroter et al., 2006; Sumathipala et al., 2008), the validity of the data collected may be affected in several ways such that information on ethical protection by authors may have been omitted by journals during publishing owing to word restrictions.

3.13 Ethical issues related to this research

The ethical issues of this study are relatively minor because all the data sourced were in the public domain in published articles, so the main ethical issue was careful acknowledgement of all sources to avoid plagiarism. However, exemption from ethics review for this study was obtained from the University of KwaZulu-Natal (UKZN) Biomedical Research Ethics Committee (BREC) with reference number, EXM093/19 (Appendix 2).

CHAPTER 4: RESULTS

In this study, electronic versions of articles from each of the five target Nigerian journals (Table 1); Annals of Ibadan Postgraduate Medicine (*AIPM),* African Journal of Reproductive Health *(AJRH),* Journal of Community Medicine and Primary Health Care *(JCMPH),* Journal of Medicine and Biomedical Research *(JMBR) and* Nigerian Journal of Clinical Practice *(NJCP)* were obtained according to the specified eligibility criteria. Articles in which Research Ethics Committee (REC) approval and informed consent were not considered to be necessary by the study investigator were excluded. These included; review articles, systematic reviews, meta-analyses, ecological studies, articles describing outbreak analysis, secondary analysis of published data, laboratory-based studies not using patients or patient material, and clinical audit or quality improvement. The eligible articles were then read in detail and the information in the tables was extracted and recorded for each eligible article. Articles were categorised into one of fourteen study designs.

Information extracted from articles was the following: Journal name, study design (randomised controlled trial, case-control, cohort, cross-sectional, case report, case series, qualitative, surveillance studies), type of patient data collected, whether the study used data collected as part of a study reported elsewhere and whether this study was referenced, disease or condition under study, population under study and whether it was considered a vulnerable population, country where study was conducted, whether the study was approved by a REC, whether the REC was named and how the authors obtained informed consent.

4.1 Graphical presentation of % distribution of research designs in five selected online journals:

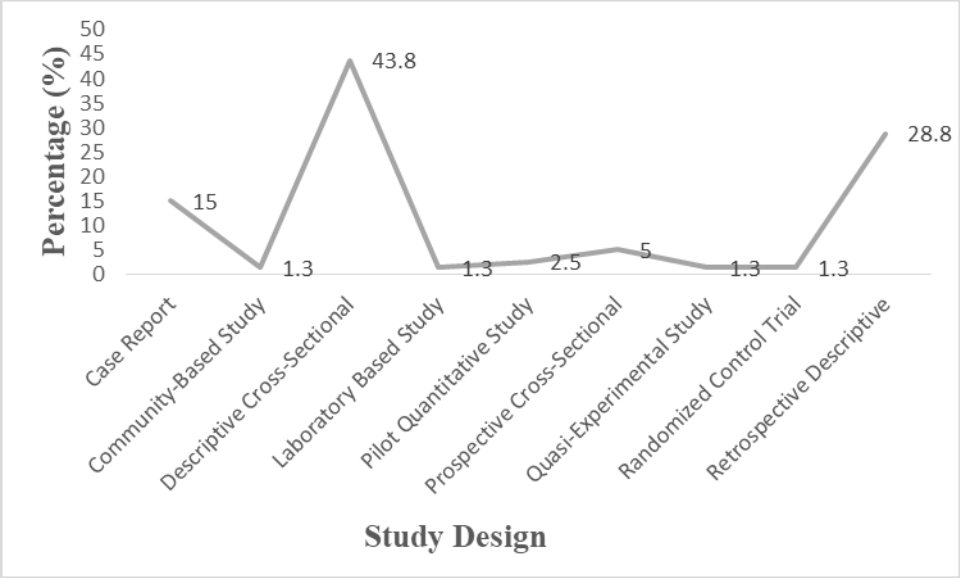

Figure 1: Percentage distribution of research designs employed in articles published in *AIPM*

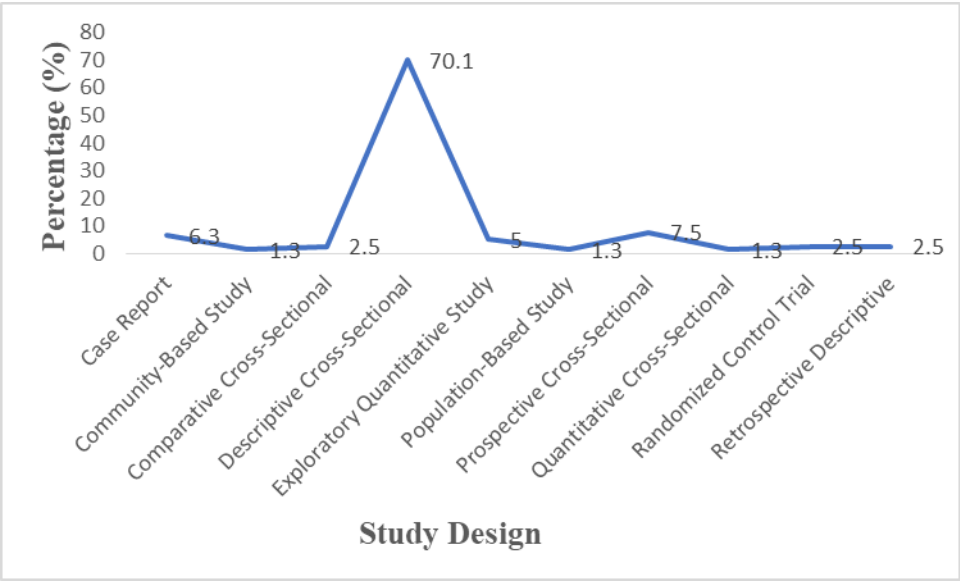

Figure 2: Percentage distribution of research design employed in articles published in *AJRH*

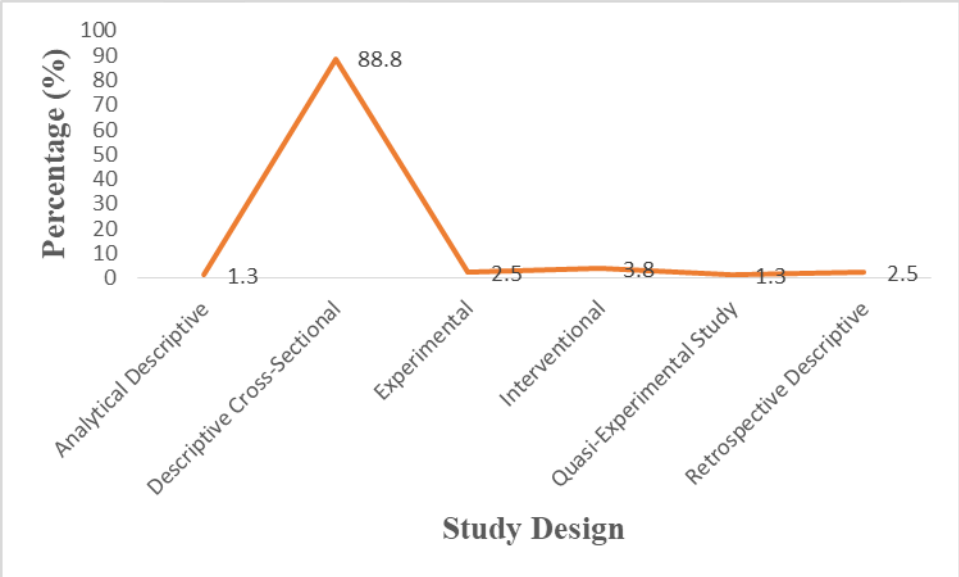

Figure 3: Percentage distribution of research design employed in articles published in *JCMPH*

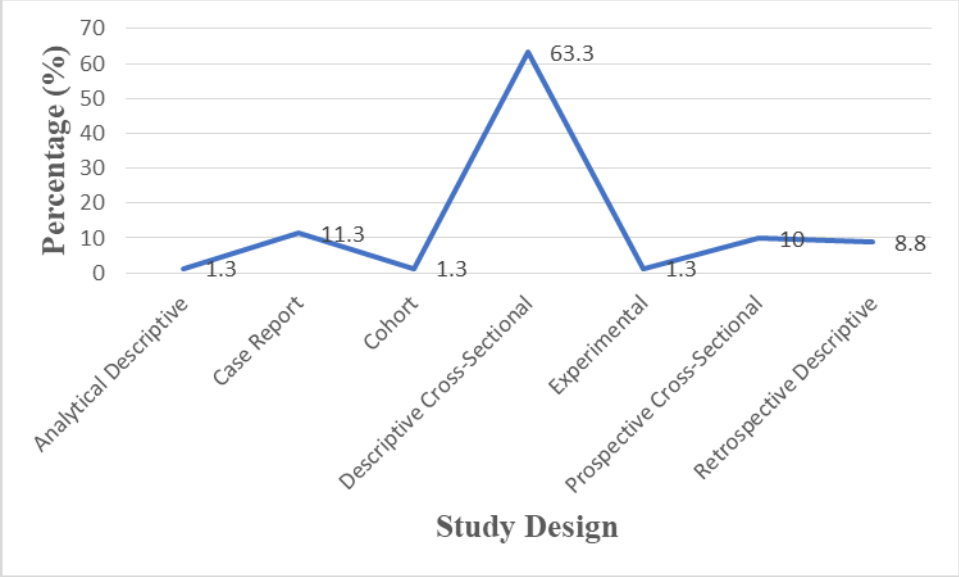

Figure 4: Percentage distribution of research design employed in articles published in *JMBR*

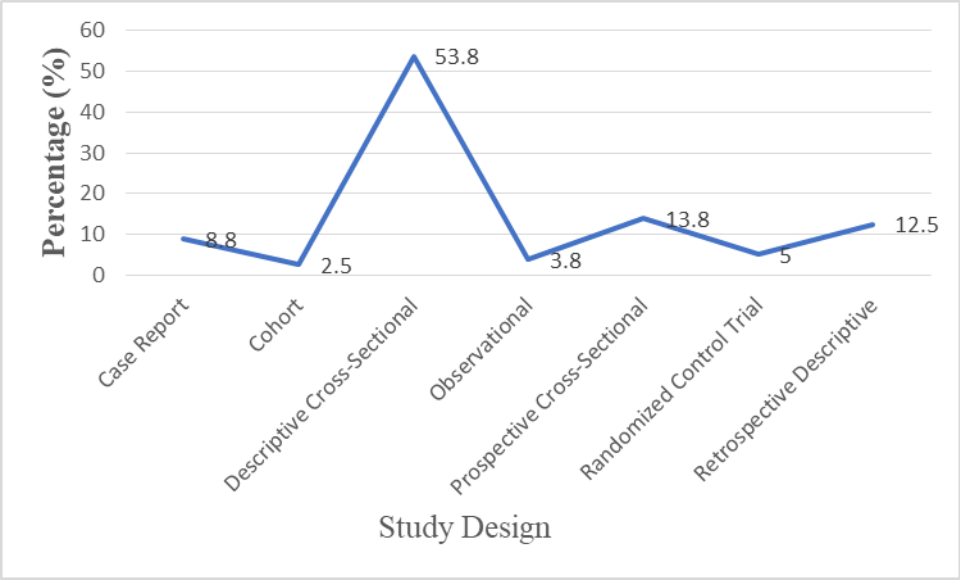

Figure 5: Percentage distribution of research design employed in articles published in *NJCP*

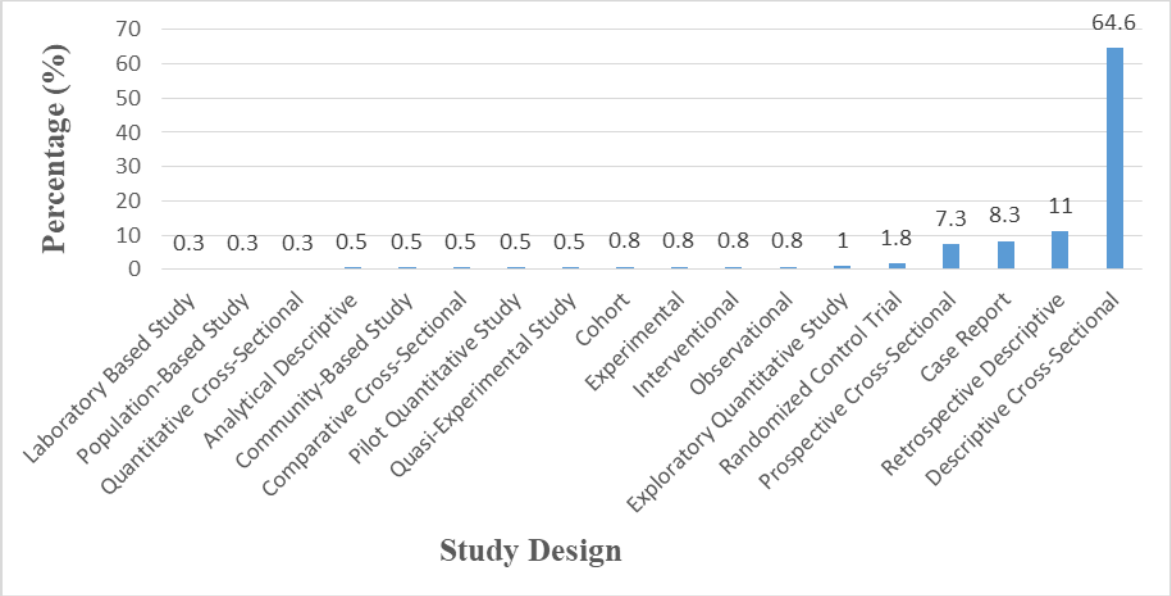

Figure 6: Overall distribution of research designs adopted across the five journals

Table 1: Sample: Journals articles published 2007–2017

Journal	Frequency	Percentage (%)
AIPM	80	20
AJRH	80	20
JCMPH	80	20
JMBR	80	20
NJCP	80	20
TOTAL	**400**	**100**

4.2 Reporting of journal articles published 2007–2017

Table 1 indicates that within the 10 years of this study period, a total of 400 research articles that met the inclusion criteria were reviewed for the study across five journals. Eighty eligible journal articles were selected from each of the five journals and consequently each journal contributed 20% of the total number of journal articles included in the study.

Table 2: Research designs employed

Study design	Frequency (n)	Percentage (%)
Descriptive Cross-Sectional	258	64.6
Retrospective Descriptive	44	11
Case Report	33	8.3
Prospective Cross-Sectional	29	7.3
Randomized Control Trial	7	1.8
Exploratory Quantitative Study	4	1.0
Cohort	3	0.8
Experimental	3	0.8
Interventional	3	0.8
Observational	3	0.8
Analytical Descriptive	2	0.5
Community-Based Study	2	0.5
Comparative Cross-Sectional	2	0.5
Pilot Quantitative Study	2	0.5
Quasi-Experimental Study	2	0.5
Laboratory Based Study	1	0.3
Population-Based Study	1	0.3
Quantitative Cross-Sectional	1	0.3
Total	**400**	**100.0**

4.3 Reporting of research designs employed

Table 2 revealed that most of the articles 258 (64.6%) in the sampled journals employed the descriptive cross-sectional design. Besides, 44 (11%) of the articles employed retrospective descriptive design while 33 (8.3%) other articles employed case report. Also, 29 (7.3%) employed

prospective cross-sectional, 7 (1.8%) employed randomized control trial, 4 (1.0%) employed exploratory quantitative study. In addition, 3 (0.8%) articles each employed experimental, interventional and observational designs. The table also indicated that 2 (0.5%) employed either analytical descriptive, community-based study, comparative cross-sectional, pilot quantitative study and/or quasi-experimental study designs while the least 1 (0.3%) employed laboratory-based study, population-based study and /or quantitative cross-sectional respectively

Table 3: Journal and study designs employed

S/N	Journal	Study design	Frequency (*n*)	Percentage (%)
1	*AIPM*	Descriptive Cross-Sectional	35	43.8
		Retrospective Descriptive	23	28.8
		Case Report	12	15.0
		Prospective Cross-Sectional	4	5.0
		Pilot Quantitative Study	2	2.5
		Community-Based Study	1	1.3
		Laboratory Based Study	1	1.3
		Quasi-Experimental Study	1	1.3
		Randomized Control Trial	1	1.3
		Total	**80**	**100.0**
2	*AJRH*	Descriptive Cross-Sectional	56	70.1
		Prospective Cross-Sectional	6	7.5
		Case Report	5	6.3
		Exploratory Quantitative Study	4	5.0
		Comparative Cross-Sectional	2	2.5
		Randomized Control Trial	2	2.5
		Retrospective Descriptive	2	2.5
		Community-Based Study	1	1.3
		Population-Based Study	1	1.3
		Quantitative Cross-Sectional	1	1.3
		Total	**80**	**100.0**
3	*JCMPH*	Descriptive Cross-Sectional	71	88.8
		Interventional	3	3.8
		Experimental	2	2.5
		Retrospective Descriptive	2	2.5
		Analytical Descriptive	1	1.3
		Quasi-Experimental Study	1	1.3
		Total	**80**	**100.0**
4	*JMBR*	Descriptive Cross-Sectional	53	63.3
		Case Report	9	11.3
		Prospective Cross-Sectional	8	10.0
		Retrospective Descriptive	7	8.8
		Analytical Descriptive	1	1.3
		Cohort	1	1.3
		Experimental	1	1.3
		Total	**80**	**100.0**
5	*NJCP*	Descriptive Cross-Sectional	43	53.8
		Prospective Cross-Sectional	11	13.8
		Retrospective Descriptive	10	12.5
		Case Report	7	8.8
		Randomized Control Trial	4	5.0
		Observational	3	3.8
		Cohort	2	2.5
		Total	**80**	**100.0**

4.4 Reporting of journal and study designs employed

Table 3 shows that in the first journal *AIPM*, the descriptive cross-sectional design 35 (43.8%) was the most frequently employed, this was closely followed by retrospective descriptive 23 (28.8%), followed by case report 12 (15.0%), followed by prospective cross-sectional 4 (5.0%) and pilot quantitative study 2 (2.5%) while community-based study 1 (1.3%), laboratory based study 1 (1.3%), quasi-experimental study 1 (1.3%) and randomized control trial 1 (1.3%) were the least employed.

In the second journal *AJRH* the table shows that 56 (70.1%) of the articles employed the descriptive cross-sectional, followed by prospective cross-sectional 6 (7.5%) followed by case report 5 (6.3%), followed by exploratory quantitative study 4 (5.0%), followed by comparative cross-sectional 2 (2.5%), randomized control trial 2 (2.5%), retrospective descriptive 2 (2.5%) while the community-based study and quantitative cross-sectional 1 (1.3%) were the least employed.

In the third journal *JCMPH*, more than two-third 71 (88.8%) employed the descriptive cross-sectional, followed by interventional 3 (3.8%), experimental 2 (2.5%), retrospective descriptive 2 (2.5%), analytical descriptive 1 (1.3%) and quasi-experimental study 1 (1.3%).

In the fourth journal *JMBR*, 53 (63.3%) employed descriptive cross-sectional, followed by case report 9 (11.3%), followed by prospective cross-sectional 8 (10.0%), followed by retrospective descriptive 7 (8.8%) while the least employed designs were analytical descriptive1 (1.3%), cohort 1 (1.3%) and experimental 1 (1.3%) respectively.

In the last journal *NJCP*, most of the articles 43 (53.8%) employed the descriptive cross-sectional design followed by prospective cross-sectional 11 (13.8%), retrospective descriptive 10 (12.5%). others include case report 7 (8.8%), followed by randomized control trial 4 (5.0%), followed by observational design 3 (3.8%) while cohort 2 (2.5%) was the least employed designs.

Table 4: Mention of informed consent, research ethics approval or both

S/n	Journal	Informed consent (%)	Research ethics approval (%)	Both ethics & informed consent (%)
1	*AIMP*	56 (70.0)	52 (65.0)	52 (65.0)
2	*AJRM*	56 (70.0)	52 (65.0)	52 (65.0)
3	*JCMPH*	63 (78.8)	53 (66.3)	47 (58.8)
4	*JMBR*	46 (57.5)	46 (57.5)	34 (42.5)
5	*NJCP*	43 (53.8)	45 (56.3)	36 (45.0)
	Total	**264**	**248**	**221**

4.5 Reporting of informed consent and research ethics approval

Table 4 shows the frequency of journals that reported informed consent, research ethics approval and both. However, of the five journals, *JCMPH* 78.8% tops the list of those who reported informed consent closely followed by *AIPM* 70% and AJRH 70%.

Regarding research ethics approval, the results show that *AIPM* and *AJRH* top the list with 65%. Also, 65% of the articles published in *AIPM* and *AJRH* secured both research ethics approval and informed consent.

Table 4 also indicates that *JMBR* was the fourth highly reported informed consent with 57.5% of the articles published in *JMBR* reporting secured informed consent and 57.5% of the articles published in JMBR reported research ethics approval as well.

On the other hand, 53.8% of published articles in *NJCP* reported informed consent while 56.3% reported research ethics approval while 45% reported both informed consent and research ethics approval respectively.

Table 5: No mentions of informed consent, research ethics approval or both

s/n	Journals	Informed consent	Research ethical approval	Both ethics & informed consent
1	*AIMP*	24 (30.0)	28 (35.0)	28 (35.0)
2	*AJRM*	24 (30.0)	28 (35.0)	28 (35.0)
3	*JCMPH*	17 (21.3)	27 (33.8)	33 (41.3)
4	*JMBR*	34 (42.5)	34 (42.5)	36 (57.5)
5	*NJCP*	37 (46.3)	35 (43.8)	44 (55.0)
	Total	**136**	**152**	**179**

Table 5 indicates that in all the journals reviewed, 21.3% of the articles published in *JCMPH* did not mention informed consent and 33.8% of articles in the same journal also did not mention research ethics approval.

The table also shows that the percentage was higher in other journals that did not mention informed consent and research ethics approval and both. In other words, a total of 136 articles across the five journals did not mention informed consent

In all, 152 articles across the reviewed journals did not mention research ethics approval, while 179 out of the 400 reviewed articles did not mention both informed consent and research ethics approval.

Table 6: Summary of data from the five journals 2007–2017

Informed Consent (%)		Research Ethics approval (%)		Both (%)	
Yes	**No**	**Yes**	**No**	**Yes**	**No**
264(66.0)	136 (34.0)	248 (62.0)	152 (38.0)	221 (55.3)	179 (44.8)

Table 6 reveals that overall 264 (66.0 %) of the articles in the five journals reported informed consent in their studies, while 248 (62.0 %) reported research ethics approval and 221 (55.3%) of the 400 articles reported both research ethics approval and informed consent.

Table 7: Comparing significant differences between frequency of reported consent, research ethics approval and both: whole sample

ANOVA						
		Sum of Squares	df	Mean Square	F	Sig.
Informed Consent	Between Groups	4.035	3	1.345	6.007	.001
	Within Groups	88.675	396	.224		
	Total	92.710	399			
Research Ethics approval	Between Groups	6.674	3	2.225	10.375	.000
	Within Groups	84.916	396	.214		
	Total	91.590	399			
Both	Between Groups	7.447	3	2.482	10.750	.000
	Within Groups	91.450	396	.231		
	Total	98.897	399			
Neither	Between Groups	2.565	3	.855	4.551	.004
	Within Groups	74.395	396	.188		
	Total	76.960	399			

4.6 Reporting the significant difference in the frequencies of reported consent, research ethics approval and both

Table 7 revealed a statistically significant difference in frequencies between reported consent ($f = 6.007$, $p<.05$); research ethics approval ($f = 10.375$, $p<.05$), and both ($f = 10.750$, $p<.05$) across the sampled journals and neither mention informed consent and research ethics approval ($f = 4.551$, $p<.05$). This suggests a significant difference in the mention of informed consent, research ethics approval and both across the sampled journals.

Table 8: Study design and reporting of consent not mentioned, research ethics approval not mentioned, and neither informed consent nor research approval reported

	Informed consent not mentioned		Research ethics approval not mentioned		Neither research ethics approval nor informed consent mentioned	
Study Design	***n* (%)**	**OR± (95% CI)**	***n* (%)**	**OR± (95% CI)**	***n* (%)**	**OR± (95% CI)**
Case Report (n = 33)	5 (15.2)	1.22 (1.024-1.447)	26 (78.8)	2.89 (0.233-37.345)	5 (15.2)	1.68 (0.249-11.322)
Descriptive Cross Sectional (n = 258)	19 (7.4)	1.05 (0.510-2.178)	17 (6.6)	1.23 (0.599-2.526)	27 (10.5)	0.85 (0.350-2.068)
Prospective Cross-Sectional (n = 29)	1 (3.5)	1.50 (0.117-19.178)	10 (34.5)	0.80 (0.643-0.996)	0 (0)	1.44 (1.097-1.884)
Retrospective (n = 44)	6 (13.6)	8.00 (1.592-40.204)	5 (11.4)	0.26 (0.053-1.258)	2 (4.5)	0.38 (0.047-3.034)

4.7 Reporting of research ethics approval & informed consent not mentioned and study design

As shown in Table 8, the results indicate no significant difference between study designs and informed consent not mentioned across sampled journals ($p >0.001$).

The table further shows no significant difference between study designs and Research ethics approval not mentioned across the sampled journals (p >0.001).

Lastly, the results in the table show a significant difference between retrospective study designs and neither research ethics approval nor informed consent mentioned **(**p = 0.38).

Table 9: Study design and mentions of informed consent, research ethics approval and both informed consent and research ethics approval reported

	Informed consent		**Research ethics approval**		**Both**	
	***N*(%)**	**OR± (95% CI)**	***N*(%)**	**OR± (95% CI)**	***N*(%)**	**OR± (95% CI)**
Analytical Descriptive	1 (0.25)	1.20 (1.022-1.185)	1 (0.3)	1.24 (1.026-1.187)	2 (0.5)	1.31 (1.023-1.192)
Case Control	1 (0.25)	1.20 (1.022-1.185)	1 (0.3)	1.24 (1.026-1.187)	2 (0.5)	1.31 (1.023-1.192)
Cohort	2 (0.5)	1.25 (1.119-1.189)	4 (1.1)	1.29 (1.029-1.193)	8 (2.00)	1.41 (1.112-1.197)
Cross Sectional	118 (29.5)	5.05 (2.221-4.089)	90 (22.5)	2.00 (1.69-1.89)	208 (52.0)	1.24 (1.02-1.201)
Descriptive Pre-Posttest	1 (0.25)	1.20 (1.022-1.185)	1 (0.3)	1.24 (1.026-1.187)	2 (0.5)	1.21 (1.023-1.197)
Experimental	4 (1.00)	1.09 (1.514-1.192)	4 (1.1)	1.02 (1.514-2.193)	8 (2.00)	1.01 (1.504-2.170)
Interventional	2 (0.5)	1.25 (1.119-1.189)	2 (0.5)	1.29 (0.029-1.193)	4 (1.0)	1.41 (1.112-1.197)
Observational	2 (0.5)	1.25 (1.119-1.189)	2 (0.5)	1.29 (1.029-1.189)	4 (1.0)	1.41 (1.112-1.197)
Prospective	11 (2.75)	1.87 (1.241-1.451)	7 (1.8)	1.21 (1.041-1.440)	18 (4.5)	1.25 (1.248-1.453)
Randomized Control Trial	4 (1.0)	1.32 (0.125-1.192)	4 (1.1)	1.33 (0.033-1.198)	8 (2.00)	1.48 (0.117-1.203)

Retrospective Descriptive	6 (1.5)	1.39 (1.131-1.196)	12 (3.0)	1.39 (1.038-1.203)	18 (4.5)	1.56 (1.0214-1.208)

4.8 Reporting of research ethics approval and informed consent mentioned and study design

Table 9 indicates no statistically significant difference in the study designs employed and informed consent secured (p >0.001) the table also indicated no difference in the study designs employed and research ethics approval (p >0.001). In all, both the Odd Ratios and confidence interval indicated no statistically significant difference in the study designs employed and informed consent and research ethics approval across the sampled journals.

4.9 Summary of main findings

A total of 400 eligible published online articles were evaluated from the selected Nigerian biomedical journals. The data show that 62% (248/400) of eligible articles reported research ethics approval, while 38% (152/400) articles did not mention reporting research ethics approval. The data also show that 66% (264/400) of eligible articles reported informed consent, while 34% (136/400) of articles did not mention reporting informed consent.

Regarding both research ethics approval and informed consent, 55.2% (221/400) of eligible articles mentioned both research ethics approval and informed consent, while 44.8% (179/400) of articles mentioned one or the other but not both research ethics approval and informed consent.

Research ethics approval and informed consent reporting by online biomedical and health-related journals in Nigeria are generally reported in a majority of articles describing minimal risk studies, and are less frequently reported in case report series.

CHAPTER 5: DISCUSSION OF RESULTS

As discussed earlier, the development of ethical principles relating to publication of research findings in studies involving human participants including identifiable human materials or identifiable data are to ensure safety and enhance ethical protection for the participants. The International Committee of Medical Journal Editors (*ICMJE*) and Committee on Publication Ethics (*COPE*) aims to ensure that journal editors carry out their gatekeeping role by making sure that research submitted and published in their journals strictly conforms to the applicable ethical guidelines (*COPE*, 2004; Doherty & Van De Putte, 2000; *ICMJE*, 2004).

The discussion of findings of this research is based on the three research questions raised in the review of the sampled journals as indicated below:

Research question 1: How frequently is research ethics approval reported in original published Nigerian online biomedical research articles?

Findings revealed that a total of 400 eligible online published articles were evaluated from the selected Nigerian biomedical journals. It shows that 62% (248/400) of the reviewed articles reported research ethics approval in their studies while 38% (152/400) articles did not mention reporting research ethics approval.

Research question 2: How frequently is informed consent reported in original published Nigerian online biomedical research articles?

The findings revealed that about two-thirds 66% (264/400) of the reviewed articles reported informed consent, while 34% (136/400) did not mention informed consent.

Research question 3: Did any types of studies have more or less of the above two types of reporting?

The findings indicated that 55.2% (221/400) of eligible articles mentioned both research ethics approval and informed consent, while 44.8% (179/400) of articles reviewed did not mentioned research ethics approval and informed consent.

In all, the findings indicated no statistically significant difference in the study designs employed and informed consent and research ethics approval across the sampled journals except for the few RCTs publications. Why this is so can only be ascertained by further studies that examine the nature of the RCTs and the variables studied which could be a future research topic. It is also possible that other Nigerian journals (not accessed) may contain more publications on RCTs. Also, this study showed that 66% of the reviewed articles reported informed consent compared to Schroter et al.'s 2006 study which showed that only 53% reported informed consent. Although it is possible that the current, later study, shows a temporal trend towards more detailed reporting of consent, an empirical reason for the increase cannot be determined at present and may not be attributable to a single factor. However, further study of chronological trends should be undertaken in future to establish this.

In all, the current study has contributed to the general body of knowledge and helps to appreciate the authenticity of research ethics approval and informed consent in any medical research.

5.1 Study implications, strengths and limitations

As shown in the literature review (Chapter 2), it is an international requirement that information about ethics protections such as research ethics approval and informed consent reporting are readily available for the reader and this information should be documented for all research with human participants (*COPE*, 2004; *ICMJE*, 2004; Doherty & Van De Putte, 2000).

This study found that although a majority of eligible studies in the five Nigerian journals studied reported research ethics approval and informed consent, 38% of articles did not report research

ethics approval, 34.8% did not report informed consent and 44.8% did not report both, showing room for improvement. This data provides evidence of the need for stronger emphasis on reporting these ethical issues by authors, journal reviewers and editors in the articles reviewed in this study. This accords with some previous similar studies (World Health Organization, 2009).

Studies have also shown that scholars may be more likely to attach importance to research ethics approval if their institutions attach importance to ethical clearance for biomedical and health research involving human participants (Mikhael, 2014). While a high proportion of articles adequately reported research ethics approval, many failed to report Informed Consent by participants (Junjira et al., 2019).

Although many journals, including those in this study, now provide guidance on including information on ethics approval and obtaining informed consent in their instructions to authors, the data suggest that many do not appear to enforce these requirements effectively.

Like the Schroter et al. 2006 study, this study is the first in series in looking into Nigerian online published medical and biomedical journals at the reporting of ethical protections. Its strengths are that it reviewed articles from several journals and did not focus on one type of study design, medical speciality or particular patient population. The number of articles selected was also large enough to evaluate differences between Nigerian medical and biomedical journals.

The major limitation of this study was that relatively few studies reporting RCTs were accessed, and some journals had restricted access. However, the volume of publications from the selected journals created a sample size acceptable for this study and may therefore not necessitate including additional journals. Also, generalisation of the findings may be limited as only five Nigerian AJOL-supported biomedical journals were reviewed as the journals selected were not representative of all biomedical journals in Nigeria.

5.2 Conclusion/recommendation

Journal editors should introduce effective mechanisms to ensure that this information (REC approval and Informed Consent) is reported for all research with human participants. It is therefore imperative for journal editors to play key roles in advocating the importance of reporting research ethics approval and informed consent by strictly enforcing high ethics approval and informed consent reporting standards and refusing the publication of articles that fail to comply with these rules (Junjira et al., 2019).

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APPENDICES

Appendix 1

DATA CAPTURE SHEET

Name of Journal: _____

S/No	Author's Name(s)	Title of Article	Year of Publication	Study Design	Informed Consent Mentioned? Yes/No	Ethics Review Mentioned? Yes/No

Appendix 2

BREC LETTER

UNIVERSITY OF
KWAZULU-NATAL
INYUVESI
YAKWAZULU-NATALI

RESEARCH OFFICE
BIOMEDICAL RESEARCH ETHICS ADMINISTRATION
Westville Campus
Govan Mbeki Building
Private Bag X 54001
Durban
4000
KwaZulu-Natal, SOUTH AFRICA
Tel: 27 31 2604769 - Fax: 27 31 260-4609
Email: BREC@ukzn.ac.za
Website: http://research.ukzn.ac.za/Research-Ethics/Biomedical-Research-Ethics.aspx

25 February 2019

Dr JE Alimasunya (213569744)
School of Applied Human Sciences
College of Humanities
Aliman_joe@yahoo.com

Dear Dr Alimasunya

Protocol: Evaluating ethics approval and informed consent reporting in selected online Nigerian Medical Journals
Degree: MSocSc
BREC REF: EXM093/19

I refer to your application to BREC received 14 February 2019 and wish to advise you that exemption of ethics review has been granted for this study.

Please ensure that you have Postgraduate approval for your protocol before commencing with your research.

This exemption will be noted at the next Biomedical Research Ethics Committee meeting to be held on 12 March 2019.

Yours sincerely

[redacted]

Prof V Rambiritch
Chair: Biomedical Research Ethics Committee

cc: (supervisor) wassenaar@ukzn.ac.za

Appendix 3

POSTGRADUATE PROPOSAL APPROVAL LETTER

Thursday, 25 April 2019

TO WHOM IT MAY CONCERN

This letter serves to confirm that Dr JE Alimasunya (213569744) proposal was tabled and approved by the School of Applied Human Sciences Research and Higher Degrees Committee on the 25 April 2019.

Yours sincerely,

[redacted]

Prof Ruth Teer-Tomaselli
Academic Leader: Research and Higher Degrees

School of Applied Human Sciences

Postal Address: Private Bag X01, Scottsville, Pietermaritzburg3209, South Africa

Telephone: +27 (0)33 260 5549 **Email:** [redacted] **Website:** psychology.ukzn.ac.za

Founding Campuses: Edgewood Howard College Medical School Pietermaritzburg Westville

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